

Nos. 23-1864, 23-1940

**United States Court of Appeals
for the Federal Circuit**

SHOCKWAVE MEDICAL, INC.,

Appellant,

v.

CARDIOVASCULAR SYSTEMS, INC.,

Cross-Appellant.

KATHERINE K. VIDAL, Under Secretary of Commerce for Intellectual Property
and Director of the United States Patent and Trademark Office,

Intervenor.

Appeal from the United States Patent and Trademark Office,
Patent Trial and Appeal Board in No. IPR2019-00405;
Administrative Patent Judges Richard Marschall,
Avelyn Marie Ross, and Mitchell G. Weatherly.

**PRINCIPAL AND RESPONSE BRIEF OF
CROSS-APPELLANT CARDIOVASCULAR SYSTEMS, INC.**

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December 14, 2023

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Claim 1 of U.S. Patent No. 8,956,371 provides (Appx200):

1. An angioplasty catheter comprising:

an elongated carrier sized to fit within a blood vessel, said carrier having a guide wire lumen extending therethrough;

an angioplasty balloon located near a distal end of the carrier with a distal end of the balloon being sealed to the carrier near the distal end of the carrier and with a proximal end of the balloon defining an annular channel arranged to receive a fluid therein that inflates the balloon; and

an arc generator including a pair of electrodes, said electrodes being positioned within and in non-touching relation to the balloon, said arc generator generating a high voltage pulse sufficient to create a plasma arc between the electrodes resulting in a mechanical shock wave within the balloon that is conducted through the fluid and through the balloon and wherein the balloon is arranged to remain intact during the formation of the shock wave.

CERTIFICATE OF INTEREST

Case Numbers: 23-1864, 23-1940

Short Case Caption: Shockwave Medical, Inc. v. Cardiovascular Systems, Inc.

Filing Party/Entity: Cardiovascular Systems, Inc., Cross-Appellant

I certify the following information and any attached sheets is accurate and complete to the best of my knowledge.

Date: December 14, 2023 Signature: /s/ Gabriel K. Bell
Name: Gabriel K. Bell

1. **Represented Entities.** Provide the full names of all entities represented by undersigned counsel in this case. Fed. Cir. R. 47.4(a)(1).

Cardiovascular Systems, Inc.

2. **Real Party in Interest.** Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. Fed. Cir. R. 47.4(a)(2).

None.

3. **Parent Corporations and Stockholders.** Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. Fed. Cir. R. 47.4(a)(3).

Cardiovascular Systems, Inc., is wholly owned subsidiary of Abbott Cardiovascular Systems Inc.

Abbott Cardiovascular Systems Inc. is a wholly owned subsidiary of Abbott Vascular, Inc.

Abbott Vascular, Inc., is a wholly owned subsidiary of Abbott Laboratories, a publicly traded company.

4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

Barnes & Thornburg LLP: Mark C. Nelson, Juanita DeLoach, Jeffrey Stone

5. Related Cases. Other than the originating case(s) for this case, are there related or prior cases that meet the criteria under Fed. Cir. R. 47.5(a)?

No.

If yes, concurrently file a separate Notice of Related Case Information that complies with Fed. Cir. R. 47.5(b). Please do not duplicate information. This separate Notice must only be filed with the first Certificate of Interest or, subsequently, if information changes during the pendency of the appeal. Fed. Cir. R. 47.5(b).

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

None/Not Applicable.

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STATEMENT OF RELATED CASES

Pursuant to Federal Circuit Rule 47.5, counsel for Cross-Appellant Cardiovascular Systems, Inc. (“CSI”) state that there have been no other appeals in or from this action previously before any appellate court. CSI is not aware of any other case pending in this or any other court or agency that will directly affect or be directly affected by this Court’s decision in this case.

However, Shockwave Medical, Inc. (“Shockwave”) previously identified as related the following matters between the same parties:

- *Shockwave Med., Inc. v. Cardiovascular Sys., Inc.*, No. 20-2251, 2022 WL 151988 (Fed. Cir. Jan. 18, 2022) (Prost, Chen, Hughes, JJ.) (per curiam) (affirming IPR2019-00409).
- *Shockwave Med., Inc. v. Cardiovascular Sys., Inc.*, No. 20-2314, 2022 WL 151990 (Fed. Cir. Jan. 18, 2022) (Prost, Chen, Hughes, JJ.) (per curiam) (affirming IPR2019-00408).

See Appx7. In each *inter partes review* (“IPR”) proceeding, the Patent Trial and Appeal Board (“Board”) found obvious all challenged claims of two other Shockwave patents that, like the patent at issue here, covered intravascular lithotripsy (“IVL”) systems. This Court summarily affirmed.

STATEMENT OF JURISDICTION

On February 2, 2023, the Board issued its Final Written Decision on Rehearing in IPR proceeding under review, finding obvious all claims of U.S. Patent No. 8,956,371 (“371 patent”) (Appx187-201) except claim 5. Shockwave’s request for director review was denied on March 30, 2023. The Board had jurisdiction per 35 U.S.C. §§ 6 and 318(a). Shockwave timely appealed on May 1, 2023, and CSI timely cross-appealed as to claim 5 on May 15, 2023. This Court has jurisdiction under 28 U.S.C. § 1295(a)(4)(A) and 35 U.S.C. §§ 141(c) and 319.

On June 23, 2023, Shockwave moved to dismiss the cross-appeal for lack of standing. ECF No. 16. CSI responded, and Shockwave replied. ECF Nos. 20, 21, 23, 24. On September 19, 2023, this Court denied the motion, permitting the parties to revisit the issue in the merits briefing. ECF No. 28. In its opening brief, Shockwave again argues the cross-appeal should be dismissed. ECF No. 31 (“Br.”)

1. This Court should reject that request for the reasons discussed in CSI’s opposition to Shockwave’s motion to dismiss, ECF Nos. 20, 21, and below, *infra* at 68-71.

STATEMENT OF THE ISSUES

In the instituted IPR proceeding, the Board found claims 1-4 and 6-17 of the '371 patent obvious based on several prior art references and relied on a skilled artisan's background knowledge as reflected in other prior art and applicant-admitted prior art ("AAPA"). The issues on appeal are:

1. Whether the Board's determination that the petition satisfied the requirements under 35 U.S.C. § 311(b) for IPR-eligibility is (a) nonappealable under 35 U.S.C. § 314(d) as a threshold condition for institution or, if appealable, (b) proper under *Qualcomm Inc. v. Apple Inc.*, 24 F.4th 1367 (Fed. Cir. 2022), which reiterated AAPA can show background knowledge and teach claim limitations in IPRs.
2. Whether the Board properly (a) construed the term "angioplasty balloon" based on the intrinsic and extrinsic record, correctly rejecting Shockwave's overly narrow interpretation, and (b) found obviousness under either construction.
3. Whether substantial evidence supports the Board's factual findings that (a) a skilled artisan would have been motivated to incorporate an angioplasty balloon and guidewire lumen into Levy, (b) Levy and other references disclose shockwaves, and (c) Shockwave's alleged objective indicia of non-obviousness were insufficient.
4. Whether the Board properly exercised its discretion in refusing to reopen discovery three years after it closed, finding no inconsistency between CSI's

press release and CSI's arguments rebutting Shockwave's objective indicia of non-obviousness.

CSI raises the following issue on cross-appeal:

Whether the Board reversibly erred in upholding claim 5 by (a) considering Uchiyama in isolation rather than with the combined prior-art teachings and/or (b) failing to recognize that electrode placement was a mere design choice that was obvious to try.

STATEMENT OF THE CASE

A. Background On Atherosclerosis

Atherosclerosis is a health condition characterized by the buildup of fatty deposits in blood vessels. Appx1596-1697 at Appx1621 (Jensen). Over time, these deposits can harden into calcified atherosclerotic plaque and restrict blood flow through the vessel, causing coronary heart disease or vascular disease. Appx1621. These plaques are known as “stenotic lesions” or “stenoses,” and the blocking materials are referred to as “stenotic material.” Appx1621.

One common method of treating atherosclerosis is balloon angioplasty. That technique involves inserting a balloon catheter into the artery, locating the balloon at the stenotic lesion, and inflating the balloon with fluid to disrupt or push aside the obstructing stenotic materials, thereby widening the artery and improving blood flow. Appx1621-1622. A typical balloon catheter consisted of a balloon formed about a hollow carrier (a lumen), which was inserted over a wire to guide it into the correct position. *See* Appx1622 (“Balloon angioplasty systems fitted over a guidewire w[ere] introduced in the 1980s as ‘Over-the-Wire’ systems....”); Appx190 ('371 patent Fig. 1), Appx199 (3:66-4:2) (disclosing “typical prior art over-the-wire” balloon catheter); Appx1818-1842 (Hayes Pat. 7,309,324); Appx3855-3860 (Healy Pat. 6,364,894).

Balloon angioplasty had certain known disadvantages, including the potential

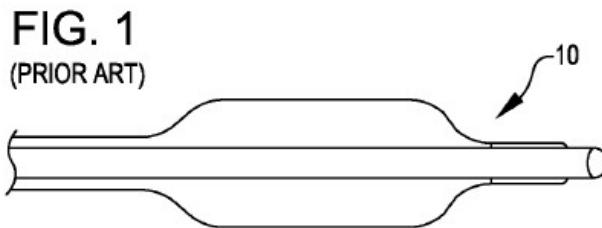
for injury to the vessel walls due to rapid, uncontrolled expansion of the balloon when the calcified lesion broke. *See Appx1623* (Jensen ¶ 83); *Appx198* ('371 patent at 1:31-36). But there was a known solution: using shockwaves to disrupt the lesion (a technique called “lithotripsy”) reduced the need for pressure in the balloon because shockwaves penetrate the soft tissue of the blood vessel or other structure without harming surrounding soft tissue. *Appx1624*, *Appx1627* (Jensen ¶¶ 84, 86). Typically, shockwaves were delivered through a liquid, and it was well-known that they could be generated using a pair of electrodes (known as “electrohydraulic lithotripsy” or “EHL”). *See Appx1633-1641* (Jensen ¶¶ 97-107); *Appx3989-3999* (Jensen Supp. ¶¶ 32-43); *Appx350-354* (Pet.).

For example, by the 1980s, prior art—such as Uchiyama and Willneff—disclosed using electrodes to generate shockwaves in a balloon filled with fluid such as saline to break apart calcified deposits in kidneys, urinary ducts, and other parts of the body by transporting the shockwaves through the fluid to the deposits. *Appx1783* (Uchiyama); *Appx1797* (Willneff). Similarly, in 1993, Levy described using laser-generated shockwaves to disintegrate calcified plaque in blood vessels and other body passages. *Appx1733-1757* (Levy) (incorporating *Appx3654-3658* (U.S. Patent No. 5,116,227 (“Levy ‘227”))); *see also Appx1951* (1:16-30) (1992) (“lithotripsy” was “frequently” used); *Appx7855*. Thus, decades before the '371 patent, it was well-known that shockwaves could be used safely.

B. The '371 Patent

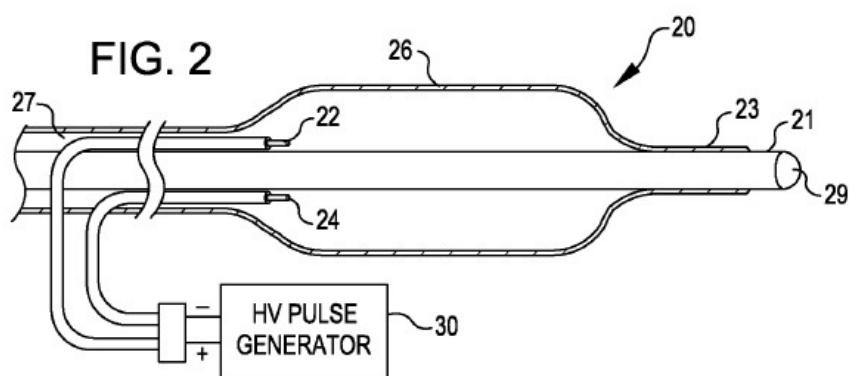
The '371 patent describes a shockwave balloon catheter. The patent, entitled “Shockwave Balloon Catheter System,” issued in 2015 based on an application filed in 2009. Appx187.

The '371 patent admits that “over-the-wire angioplasty balloon catheter[s]” such as those depicted in Figure 1 were “typical” in “prior art”:



Appx190; *see* Appx199 (3:66-4:2) (“FIG. 1 is a view of the therapeutic end of a typical prior art over-the-wire angioplasty balloon catheter **10**. Such catheters are usually non-compliant with a fixed maximum dimension when expanded with a fluid such as saline.”).

The claimed invention only purports to add electrodes and a pulse generator, as illustrated in Figure 2:



Appx190. The patent explains that “electrodes … within the fluid filled balloon … are attached to a source of high voltage pulses.” Appx199 (4:10-13). The electrodes produce electrical arcs that “are used to generate shock waves in the fluid.” Appx199 (4:17-18). The shockwaves are “conducted through the fluid [in the balloon], through the balloon, through the blood and vessel wall to the calcified lesion where the energy will break the hardened plaque without the application of excessive pressure by the balloon on the walls of the artery.” Appx199 (4:36-41).

Claim 1, which is representative for purposes of this appeal, recites:

1. An angioplasty catheter comprising:

an elongated carrier sized to fit within a blood vessel, said carrier having a guide wire lumen extending therethrough;

an angioplasty balloon located near a distal end of the carrier with a distal end of the balloon being sealed to the carrier near the distal end of the carrier and with a proximal end of the balloon defining an annular channel arranged to receive a fluid therein that inflates the balloon; and

an arc generator including a pair of electrodes, said electrodes being positioned within and in non-touching relation to the balloon, said arc generator generating a high voltage pulse sufficient to create a plasma arc between the electrodes resulting in a mechanical shock wave within the balloon that is conducted through the fluid and through the balloon and wherein the balloon is arranged to remain intact during the formation of the shock wave.

Appx200.

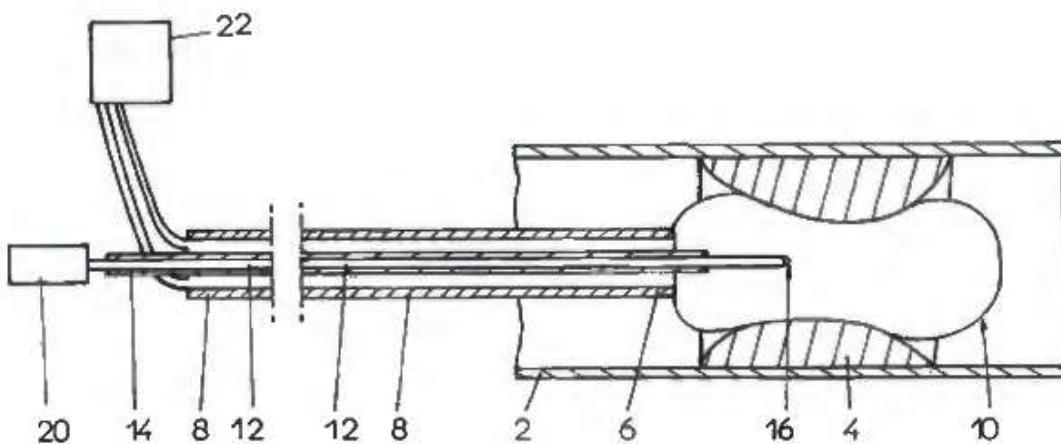
Claim 5 (the only other claim relevant to this appeal) recites: “the pair of electrodes is disposed adjacent to and outside of the guide wire lumen.” Appx200.

C. Prior Art

The prior art at issue in this appeal includes several patents and patent applications: Levy, Mantell, Uchiyama, Willneff, and others. Appx2-4.

1. Levy

Levy, dated 1993, describes using laser-generated shockwaves to disintegrate calcified plaque in blood vessels. Appx1733-1757. Levy discloses a catheter (8) with a lumen housing an optical fiber (12) connected with a laser light source (20) capable of producing laser pulse beams of suitable duration and energy, as shown in Levy's Figure 1:



Appx1743, Appx1737.

Levy teaches that an inflatable body (10) is a balloon of the kind used with catheters to perform treatments in blood vessels. Appx1737. The device is inserted into a blood vessel (2) where a deposit (4) such as a plaque or atheroma has developed. Appx1737. Fluid from a supply source 22 inflates the balloon until it

touches the exposed surface of the deposit but without producing a force that would cause the vessel to expand. Appx1737. The laser source then produces laser beam pulses in the fluid within the balloon. Appx1738. The pulsed energy emissions create a plasma that forms and cavitates vapor within the liquid, producing an implosion of gas bubbles for each laser beam pulse. Appx1738. The resulting shockwaves travel through the fluid and the walls of the balloon to disintegrate the deposit. Appx1738.

Levy incorporates by reference details about laser pulses and shock waves from another patent, Levy '227. Appx1735, Appx1737. Levy '227 issued in 1992 and teaches cleaning blood vessels using "shock waves resulting from the laser radiation pulses, producing vapor implosions which detach debris or tissue" from blood vessel walls. Appx3654, Appx3657 (3:39-42); *see* Appx3657 (4:64-66) ("[T]he technique can also be employed in the medical field for cleaning vessels, such as blood vessels, for example to remove plaque deposits, or atheromas.").

So, by at least 1993, a skilled artisan knew that it was possible to address calcified deposits in blood vessels using shockwaves.

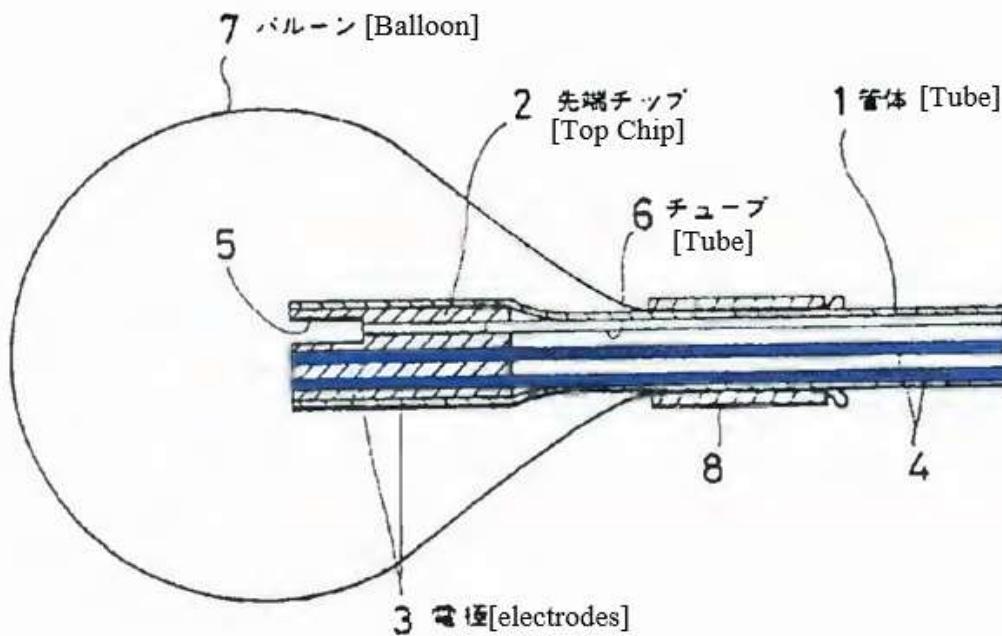
2. Mantell

Mantell, filed in May 2009, describes a shockwave lithotripsy probe that creates shockwaves in liquid to break up concretions in blood vessels. Appx1758-1781 at Appx1776 (¶ 20). The device is threaded through a center lumen of a

catheter or balloon device and delivered to “a proper channel of a heart.” Appx1776 (¶ 21). Electrodes inside a saline-filled balloon create arcs that “cause[] a steam bubble in the liquid [that] … rapidly expands and contracts back on itself” to generate “a shockwave.” Appx1777 (¶ 29).

3. Uchiyama

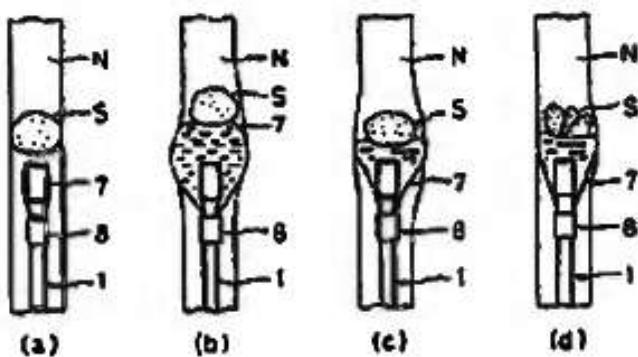
Uchiyama, dated 1986, similarly describes an arc-based shockwave generator inside an inflatable balloon for use in blood vessels. Appx1782-1792 at Appx1783-1785. A pair of electrodes (3, blue) are near the end of a tube inside the balloon, as in Drawing 1:



第 1 図
[Drawing 1]

Appx1791 (annotated); *see* Appx1786; Appx69.

The device is inserted and placed near a calculus in the body:



Drawing3

Appx1786. The electrodes then generate shockwaves “inside of the balloon[7]” and their impact is transmitted “via the fluid” to break up the calculus. Appx1784-1785.

4. Willneff

Willneff, published in 1982, describes a “shock wave generator for medical applications.” Appx1793-1817 at Appx1794. Electrodes generate shockwaves within a balloon to remove concretions from the urinary tract. Appx1796-1797.

D. Board Proceedings

1. CSI’s Petition

On December 7, 2018, CSI sought IPR of all 17 claims in the ’371 patent. The petition asserted 15 grounds. Appx320-394 (Pet.); Appx2-4. Seven grounds involved “Levy as modified by AAPA in combination with” one or more other references including, among others, Mantell, Uchiyama, Willneff, and Hayes. Appx337-338. The other eight grounds swapped Levy for Willneff. Appx338.

The petition observed that the '371 patent itself describes a “typical prior art over-the-wire angioplasty balloon catheter [that] is the same as disclosed in numerous [prior-art] references, including Healy and Hayes.” Appx355. “Accordingly, for the sake of brevity,” the petition “refer[red] to the typical prior art over-the-wire angioplasty balloon catheter described in the '371 patent and as disclosed in Healy and Hayes” as “AAPA.” Appx355. The petition further explained that “the '371 patent offers routine design modifications to existing angioplasty catheter devices utilizing shockwaves to achieve known and predictable results.” Appx341.

For claim 5, the petition explained that Levy when combined with Mantell, Uchiyama, or Willneff and in light of the AAPA rendered obvious the claimed electrode position (“adjacent to and outside of the guide wire lumen,” Appx200 (cl. 5)). Appx363; *see* Appx1784-1786 (Uchiyama); Appx1653 (Jensen ¶¶ 132-33); Appx3962-4097 at Appx4071-4072 (Jensen Supp. ¶ 144); Appx7358-7359 (Jensen drawings); Appx718-769 at Appx755 (Reply); Appx4235-4237 (Berger Dep.). The petition explained: (i) Uchiyama “discloses a shockwave generator including a pair of electrodes (3) that are disposed radially spaced away from the lumen of tube (8),” and, in any event, (ii) it “would have been obvious to a POSITA to implement the features of Uchiyama to provide the pair of electrodes” outside and adjacent to the lumen as it was “a routine design choice and well within [a skilled artisan’s]

knowledge and know-how.” Appx363-364. Either way, the petition explained, a skilled artisan would have found it obvious, in the overall combination, to place electrodes outside of and adjacent to the lumen. Appx363-364.

On July 9, 2019, the Board instituted IPR. Appx535-562. Shockwave filed its Patent Owner’s Response (“POR”); CSI filed its Reply; and Shockwave filed its Sur-reply. Appx4. On April 15, 2020, the Board heard argument. Appx976-1078.

2. The Board’s Final Written Decision And Rehearing Grant

On July 8, 2020, the Board issued a Final Written Decision holding that claims 1-4 and 6-17 of the ’371 patent were obvious; only claim 5 survived. Appx98-186. The Board relied on Levy and several prior art references in addition to AAPA. Appx116-121. In doing so, the Board determined that AAPA qualified as “prior art consisting of patents or printed publications” under § 311(b). *See* Appx132-133.

On August 18, 2020, the PTO issued binding guidance (“AAPA Guidance”) stating that AAPA is not “prior art consisting of patents or printed publications” under § 311(b). Appx10735-10738. So the Board *sua sponte* initiated rehearing “to allow the panel to consider and follow the AAPA Guidance.” Appx1079-1082 at Appx1081. The Board permitted the parties to submit additional briefing but ordered that “neither party may submit additional evidence.” Appx1083-1086 at Appx1085; *see* Appx5, Appx86.

On February 1, 2022, in a separate matter (*Qualcomm*), this Court agreed with the PTO’s AAPA Guidance, holding that AAPA is not “prior art consisting of patents or printed publications” under § 311(b). 24 F.4th at 1373. This Court, therefore, held that AAPA cannot be “the ‘basis’” of an IPR petition: it is “impermissible for a petition to challenge a patent relying on *solely* AAPA without also relying on a prior art patent or printed publication.” *Id.* at 1377 (emphasis added). But this Court also emphasized that ““it *is* appropriate to rely on” AAPA in finding obviousness: “[a]dmissions in the specification regarding the prior art are binding on the patentee” and relevant to “the general knowledge of a skilled artisan.” *Id.* at 1375-76 (emphasis added) (quoting *Koninklijke Philips N.V. v. Google LLC*, 948 F.3d 1330, 1339 (Fed. Cir. 2020); *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1362 (Fed. Cir. 2007)). This Court explained that “AAPA may be used,” for example, to “furnish[] a motivation to combine or supply[] a missing claim limitation.” *Id.* at 1376 (citing *Koninklijke*, 948 F.3d at 1337-38). On June 9, 2022, the PTO issued Updated AAPA Guidance in light of *Qualcomm*. Appx6; Appx10739-10745.

On January 13, 2022, shortly before this Court summarily affirmed the invalidity of several other Shockwave patent claims (*see supra* at x), CSI issued a press release (Appx10649-10651) announcing that “it has made significant progress towards the commercialization of intravascular lithotripsy (IVL) systems.”

Appx10649. CSI explained: “[l]ithotripsy is a medical procedure that uses non-invasive high-pressure waves to fracture and disrupt pathologic solid masses,” which “has been used successfully for many years in the treatment of kidney and gall stones, and more recently has found application in treatment of calcified coronary and peripheral arteries”—i.e., in IVL systems. Appx10649. CSI stated that it completed “[f]easibility testing” on its new proprietary IVL system, which is “designed to improve upon” and supplement existing treatments. Appx10649.

On March 23, 2022, two years after discovery closed, Shockwave moved for entirely new and previously unrequested discovery, arguing that CSI’s press release (regarding CSI’s new IVL system) was somehow inconsistent with CSI’s objective-indicia arguments in the IPR (regarding prior treatments). Appx86-91.

3. The Board’s Final Written Decision on Rehearing

On February 2, 2023, the Board issued its Final Written Decision on Rehearing, again invalidating 16 of the 17 challenged claims and denying Shockwave’s motion for additional discovery. *See Appx6.*

1. Applying *Qualcomm* and the PTO’s Updated AAPA Guidance, the Board determined that the Petition does not improperly “rely[] on solely AAPA without also relying on a prior art patent,” Appx31 (quoting *Qualcomm*, 24 F.4th at 1377), and that the AAPA “demonstrate[s] the knowledge of an ordinarily skilled artisan at the time of the invention,” Appx23. The Board pointed out that CSI’s definition of

AAPA in the petition included Healy and Hayes in addition to the '371 patent's admissions and that "the well-known configuration of an angioplasty catheter[] was apparent on the face of Healy and Hayes." Appx32. In turn, the Board found that "the combined teachings of Levy" in conjunction with other prior art—including Mantell, Uchiyama, Willneff, and Hayes—"along with the background knowledge reflected in the AAPA" rendered obvious all challenged claims except claim 5. Appx28 (cl. 1), Appx66-76 (other cls.).

2. For claim 1, the Board addressed two contested limitations. First, the parties disputed the construction of the claimed "angioplasty balloon": CSI argued that it is an inflatable balloon that can be inserted to widen obstructed blood vessels, whereas Shockwave insisted that it must do so specifically by "displac[ing] the plaque into the vessel wall." Appx11 (quoting Appx598 (POR)). The Board agreed with CSI, holding that, based on the plain claim language and intrinsic record, the term means "an inflatable sac that is configured to be inserted into a blood vessel for use in a medical procedure to widen narrowed or obstructed blood vessels." Appx11-16, Appx28. The Board found that the record did not support Shockwave's narrow requirement to displace the plaque "into the vessel wall." Appx15. Thus construed, the Board found—and it was undisputed—that the Levy reference teaches an angioplasty balloon. Appx28-29. The Board also found it was undisputed that

“the AAPA describes an angioplasty balloon” under *either* construction. Appx28-

29

Second, the Board determined that Levy includes a “shockwave generator,” as claimed, because “Levy indisputably incorporates Levy ’227 by reference as describing the laser used within Levy’s balloon,” and Levy ’227 discloses use of shockwaves to clean blood vessels. Appx29-30. The Board acknowledged that CSI alternatively relied “upon each of Mantell, Uchiyama, and Willneff as describing an arc generator that creates shockwaves between electrodes positioned within a balloon as claimed,” yet Shockwave had “not respond[ed] to [CSI]’s showing.” Appx30. So the Board concluded that CSI persuasively showed that Levy, Mantell, Uchiyama, and Willneff each taught generating shockwaves in a balloon. Appx31.

3. The Board then addressed the motivation to incorporate into Levy the known guidewire and sealing arrangement depicted in “AAPA” (which, as noted, was shorthand for the prior-art configurations in the ’371 patent and the Healy and Hayes references, *supra* at 12; Appx355). The Board found that “the arrangement of a balloon sealed near the distal end of a carrier with a longitudinal lumen through which a guidewire extends was well known” because the ’371 patent admitted such ““over-the-wire”” configurations were ““typical”” and Healy and Hayes illustrated them. Appx31-32, Appx39 (citation omitted). The Board explained that a skilled artisan knew that such a guidewire “assist[ed] a physician to navigate the catheter to

reach the area for treatment.” Appx39. The Board credited Dr. Jensen’s testimony that a skilled artisan would “adapt Levy’s catheter and/or balloon design” using such a configuration “to increase the types of treatments Levy could perform.” Appx40 (quoting Appx754 (Reply), and citing Appx1645, Appx1664-1665 (¶¶ 115, 157)). The Board, therefore, found a skilled artisan would have used that typical over-the-wire configuration for Levy’s balloon. Appx40.

4. Next, the Board determined that Shockwave’s evidence of secondary considerations did not demonstrate non-obviousness. Appx47-65. At the outset, the Board found that Shockwave was not entitled to a presumption of nexus because Shockwave and its expert failed to show that its commercial device contains every claimed feature. Appx47-49. But, even assuming Shockwave showed “some degree of nexus,” the Board found Shockwave’s secondary-considerations evidence did not save its claims. Appx49. The Board detailed its findings at length.

On long-felt need, the Board explained that “none of [Shockwave]’s clinicians support any of their testimony about the benefits of Shockwave IVL over competitive devices with citations to objective evidence,” which “slightly reduce[d] the weight of the testimony from these clinicians.” Appx50-51. The Board found the clinicians’ testimony was “of modest, but meaningful, probative value on whether IVL is more effective than pre-existing options.” Appx51. After examining

the other evidence, the Board concluded that IVL is “promising,” but “previous methods for treating the same type of stenoses … remain viable.” Appx59.

On failure of others, the Board similarly explained that, “[a]lthough IVL may show signs of being able to treat certain types of coronary artery disease in a measurably more effective manner than prior techniques, [Shockwave] does not persuade us that those prior techniques are failures.” Appx60. On skepticism, the Board viewed Shockwave’s “evidence of skepticism [a]s a weak indicator of non-obviousness.” Appx60. The Board found Shockwave’s evidence of industry praise, clinician testimony, was “unsubstantiated speculation” discounted financial analyst statements, and ultimately “ascrib[ed] some, but not great, weight” to that evidence. Appx61. And on commercial success, the Board found that Shockwave’s “increased spending on sales and marketing,” not the patented features, “at least partially explain[ed] the increase in its revenues.” Appx62. It also noted that Shockwave failed to provide any evidence of market share and concluded that Shockwave’s “showing of commercial success [was] weak.” Appx64.

Overall, the Board found that Shockwave’s “objective evidence of non-obviousness is voluminous, but largely weak” and “[u]ltimately … excitement about the *potential* efficacy of the Shockwave IVL or its *potential* commercial success simply does not warrant a conclusion that claim 1 remains patentable.” Appx65.

5. Proceeding to the remaining claims, the Board concluded that claims 2-4 and 6-17 were likewise unpatentable as obvious. Appx65-67, Appx70-80. Those claims' limitations are not separately at issue here. The Board found that one claim survived: claim 5. Appx67-70. The Board determined that Uchiyama itself does not place the electrodes outside of a lumen tube, as claim 5 required, and thus upheld the claim. *See* Appx69-70.

6. Finally, the Board denied Shockwave's motion for additional discovery. Appx86-92. The Board agreed with CSI that CSI's 2022 "Press Release contains nothing that materially conflicts with the existing record" and observed that "far too many uncertainties remain about the probative value or even relevance of any evidence that might be obtained by granting the Discovery Motion." Appx91.

Shockwave's request for director review was denied. Appx1384-1386; Appx10728-10729. Shockwave now appeals. CSI cross-appeals on claim 5.

SUMMARY OF THE ARGUMENT

The Board's determination that claims 1-4 and 6-17 of the '371 patent are obvious is supported by substantial evidence. This Court should affirm.

1. Shockwave's primary argument on appeal is that the Board erred in relying on applicant-admitted prior art (AAPA). The Court should reject that argument for two independently sufficient reasons. First, the Board's decision that CSI's petition raised IPR-eligible grounds is judicially unreviewable. Second, the Board

appropriately considered the AAPA as evidence of an ordinarily skilled artisan's background knowledge under *Qualcomm*.

a. The Board's determination that CSI's petition invoked grounds eligible for IPR under 35 U.S.C. § 311(b) is a decision relating to the mandatory threshold conditions for institution of IPR, which is not appealable under § 314(d). Similar requirements have been held unreviewable, *see, e.g., Thryv, Inc. v. Click-to-Call Techs., LP*, 140 S. Ct. 1367, 1373 (2020); *Cuozzo Speed Techs., LLC v. Lee*, 579 U.S. 261, 275-76 (2016), and the same is true here.

b. Even if reviewable, the Board's reliance on AAPA was proper. In *Qualcomm*, this Court reiterated that AAPA can show background knowledge and teach claim limitations in IPRs—consistent with decades of precedent recognizing that applicants are bound by their admissions about prior art. 24 F.4th at 1375-77. The Board properly followed *Qualcomm* here, holding that the applicant's admissions in this case (uncontested facts about prior-art over-the-wire angioplasty balloon catheters) reflected the background knowledge of a skilled artisan. The Board's reliance on AAPA was especially appropriate in this case because the petition expressly used “AAPA” as *shorthand* (“for brevity”) to reference not only the applicant's admissions in the patent (as in *Qualcomm*) but also other prior art references. Appx355. Collectively, those confirmed that over-the-wire angioplasty catheters were well-known. Appx32.

2. The Board correctly construed “angioplasty balloon” based on the claim language and intrinsic record: an angioplasty balloon is inserted into a blood vessel and inflated “to widen narrowed or obstructed blood vessels.” Appx11-16. The Board correctly rejected Shockwave’s proposal to narrow that ordinary meaning to require the balloon to “displace plaque ‘*into* the vessel wall.’” Appx11. The claim language and intrinsic record refute that requirement. *See, e.g.*, Appx200 (5:31-33) (it “is not a requirement” that the balloon “expand[] to fit snugly to the vessel wall”).

On appeal, Shockwave nominally defends its proposed construction but largely side-steps it. First, Shockwave insists that its construction does not mean the balloon must displace the plaque “*into*” the wall (despite using precisely that word in its proposal) and that it was enough to press the plaque “*against*” the wall. But it told the Board something else. *See* Appx7469 (Shockwave’s expert, Berger: claims “*do[] not cover* balloons which merely press up *against* the vessel wall but do not force plaque *into* the vessel wall”). Second, Shockwave asserts that an angioplasty balloon must exert “high pressures of 10-30 atmospheres” (Br. 4)—an unpreserved and equally unsupported limitation. Third, Shockwave argues that prosecution history statements limit claim scope. But the prosecution nowhere mentions displacing plaque “*into* the vessel wall” or any such limitation. Fourth, Shockwave asserts that the Board did not give the balloon sufficient “structure.” But Shockwave

is vague about what that entails, circularly insisting it is whatever structure is necessary to perform angioplasty.

The Board's construction was correct. Moreover, the Board found that, even under Shockwave's construction, the prior art teaches the claimed angioplasty balloon. That alternative finding is supported by substantial evidence in any event.

3. Shockwave's remaining arguments challenge other Board fact-findings. Substantial evidence supports each.

a. First, the Board's conclusion that a skilled artisan would have been motivated to incorporate a "guide wire lumen" into Levy is well-supported. A guidewire lumen was an undisputedly well-known feature in the prior art, and ample evidence supports that conclusion. The Board found that including a guidewire lumen in Levy would assist a physician to navigate Levy's catheter to reach the treatment area and increase the types of treatments Levy could perform. It relied on the well-supported testimony of CSI's expert, Dr. Jensen, for each conclusion.

b. Second, the Board's conclusion that Levy discloses shockwaves is well-supported. Levy incorporates Levy '227 by reference, and Levy '227 undisputedly discloses shockwaves. The Board correctly concluded that Levy '227 discloses use of shockwaves in blood vessels because it teaches the same cavitation technique for each application it discusses, and that cavitation action results in shockwaves. Shockwave identifies no reason to disturb the Board's findings.

c. Third, as to secondary considerations, the Board properly found that Shockwave failed to justify a presumption of nexus between Shockwave's evidence and the claimed invention. And, even assuming a nexus, the Board properly weighed Shockwave's objective-indicia evidence and found it wanting. In a detailed, 15-page analysis, it considered each piece of evidence Shockwave relied on and explained its findings that the evidence did not outweigh CSI's obviousness showing. The Board explained, for example, that although Shockwave's evidence showed "genuine excitement" in the industry and favorable projections, it amounted to "unsubstantiated speculation about better efficacy" and "forward-looking statements from financial analysts or hopeful statements." Appx61. That makes this case unlike *Volvo Penta of the Americas, LLC v. Brunswick Corp.*, 81 F.4th 1202, 1215 (Fed. Cir. 2023), where the Board ignored evidence on each factor and failed to explain its reasoning or summation. The Board made none of those mistakes here.

4. The Board did not abuse its discretion in denying Shockwave's motion for previously-unrequested discovery. In instituting rehearing proceedings, the Board ordered that the record would not be reopened. Nonetheless, Shockwave asked to do just that, asserting that additional discovery was necessary because a 2022 CSI press release was contrary to arguments CSI previously made to the Board on secondary considerations. But the Board found, correctly, that there was no inconsistency. CSI's press release announced plans to develop an IVL device that

would improve upon existing options; the release observed that lithotripsy had been used successfully in other types of treatment and had found application in treatment of calcified lesions. That was consistent with CSI's arguments to the Board that alternative treatment options existed and remained viable after the release of IVL. The Board properly exercised its discretion in refusing to reopen the record.

5. Therefore, the Board's findings that claims 1-4 and 6-17 were obvious should be affirmed. But claim 5 was equally obvious. Claim 5 recites a simple design choice—the location of the electrodes (“adjacent to and outside of the guide wire lumen”).

The Board legally erred in holding otherwise for two independent reasons. First, the Board determined that one prior art reference (Uchiyama) alone failed to teach that location, failing to consider it together with the other prior art in the asserted combination. CSI's expert, for example, depicted exactly how a pair of electrodes would look when placed outside the lumen on a standard over-the-wire catheter. Appx7358-7359. The Board did not address that. Second, the Board also erred because the claimed electrode placement was a design choice that a skilled artisan would have successfully implemented and that would have been obvious to try. *See, e.g., Uber Techs., Inc. v. XOne, Inc.*, 957 F.3d 1334, 1341 (Fed. Cir. 2020) (reversing because Board committed “legal error” in “fail[ing] to recognize” that “two known, finite, predictable, solutions” were obvious).

This Court should reverse on claim 5. Before the Board, Shockwave’s counter-argument to CSI’s proposed combination for claim 5 was that the electrodes would be too close to the vessel wall, causing damage. But the Board rejected that same argument in finding the other claims obvious. So, properly considering the prior art combination as a whole, claim 5 is obvious like the other the claims.

STANDARD OF REVIEW

This Court reviews legal questions, such as claim construction and obviousness, *de novo* and underlying factual findings for substantial evidence. *Pavo Sols. LLC v. Kingston Tech. Co.*, 35 F.4th 1367, 1373 (Fed. Cir. 2022); *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2015). Substantial evidence is a “deferential standard of review” requiring only that “a reasonable mind might accept the evidence as adequate to support the finding.” *Teva Pharms. Int’l GmbH v. Eli Lilly & Co.*, 8 F.4th 1349, 1359, 1356 (Fed. Cir. 2021). If two conclusions can “reasonably be drawn from the evidence in record, the PTAB’s decision to favor one conclusion over the other … must be sustained.” *Id.* at 1359 (citation omitted). This Court will not reweigh the evidence or the Board’s credibility determinations. *Elbit Sys. of Am., LLC v. Thales Visionix, Inc.*, 881 F.3d 1354, 1358 (Fed. Cir. 2018).

The Court reviews the Board’s “decision[s] regarding management of its permissive rules governing trial proceedings”—including discovery orders—only for abuse of discretion. *Quake v. Lo*, 928 F.3d 1365, 1379 (Fed. Cir. 2019).

ARGUMENT

I. THE BOARD PROPERLY FOUND THAT OVER-THE-WIRE ANGIOPLASTY BALLOON CATHETERS WERE WELL KNOWN IN LIGHT OF THE PATENTEE'S ADMISSIONS AND PRIOR ART

Shockwave's principal argument on appeal is that the Board erred in relying on applicant-admitted prior art (AAPA) to show that inserting an angioplasty balloon catheter via a "guidewire," as claimed, was well known. Br. 18-28. But there was (and is) "no dispute" that such over-the-wire catheters were known. Appx38. Indeed, the '371 patent admits they were "typical" and depicts one in Figure 1. Appx199 (3:66-67); *see* Appx190 (Fig. 1). This Court in *Qualcomm* held that the Board can rely on such AAPA as evidence of a skilled artisan's background knowledge in finding claims obvious as long as the "basis" for the IPR is prior art patents and printed publications, 24 F.4th at 1374-77—and that is what the Board did here. The Board properly followed *Qualcomm*, and nothing in Shockwave's appeal shows otherwise.

Notably, on remand in *Qualcomm*, the Board found that the petition in that case properly invoked applicant-admitted prior art, and that issue is now back before this Court in another appeal. Regardless, the Board's finding here is even more sound because the Board relied not just on the patent's admissions for a skilled artisan's background knowledge but also on *other prior art references*—Healy and Hayes—which the petition collectively shorthanded as "AAPA." As the Board

found, those references disclose that same “well-known configuration of an angioplasty catheter,” which “was apparent on the face of Healy and Hayes.” Appx32; *see* Appx39-41 (citing Appx3855-3860 (Healy)); Appx355 (Pet.). Shockwave’s “AAPA” arguments, therefore, miss the mark.

This Court does not need to get there, though: the Board’s determination that CSI’s petition raised IPR-eligible grounds despite relying, in part, on applicant-admitted prior art relates to a threshold condition for institution that is nonappealable.

A. The Board’s Finding That The Petition Meets The Threshold IPR Requirements Under § 311(b) Is Nonappealable Under § 314(d)

Shockwave challenges the Board’s determination that the petition satisfies the requirements for IPR under § 311(b), which is a threshold condition for institution that is nonappealable under § 314(d).

A petitioner may seek IPR “only on the basis of prior art consisting of patents or printed publications.” 35 U.S.C. § 311(b). The Board may institute an IPR if “the information presented in the petition filed under [§] 311” (and any preliminary response thereto under § 312) shows a reasonable likelihood of unpatentability. *Id.* § 314(a). The Board’s decision to institute is “final and nonappealable.” *Id.* § 314(d); *see Thryv*, 140 S. Ct. at 1373. This nonappealability applies to any issue “closely related” to the Board’s decision to institute. *Cuozzo*, 579 U.S. at 275-76; *see SIPCO, LLC v. Emerson Elec. Co.*, 980 F.3d 865, 869 (Fed. Cir. 2020).

That prohibition applies to the Board’s determination on § 311(b) here. The Board found that CSI’s petition invoked proper bases under § 311(b) and “AAPA is not the ‘basis’ of its challenges.” Appx31 (quoting language from § 311(b) in *Qualcomm*, 24 F.4th at 1374). That is a decision on the “mandatory threshold conditions for institution” and, thus, is “protected … from judicial review” under § 314(d). *Apple Inc. v. Vidal*, 63 F.4th 1, 7 (Fed. Cir. 2023).

The Supreme Court and this Court have reached that conclusion as to similar determinations. In *Cuozzo*, for example, the Supreme Court held that the Board’s determination that the petition sufficiently raised the grounds “with particularity” (per 35 U.S.C. § 312(a)(3)) was nonappealable because it was “closely related” to the Board’s decision “that the ‘information presented in the petition’ warranted review.” 579 U.S. at 276. Similarly, in *Thryv*, the Court held that the Board’s determination that an IPR petition complies with the statutory time bar (per § 315(b)) was nonappealable because it is “integral to, indeed a condition on, institution.” 140 S. Ct. at 1373. So too is the Board’s determination that a petition meets the requirements of § 311. Indeed, this Court has characterized § 311 as stating “preliminary procedural requirements” that “relate more closely to the [institution] determination” than the time bar at issue in *Thryv*. *Wi-Fi One, LLC v. Broadcom Corp.*, 878 F.3d 1364, 1373 (Fed. Cir. 2018) (en banc), abrogated on other grounds

by *Thryv*, 140 S. Ct. 1367. Therefore, the Board’s decision that the petition had a sufficient “basis” apart from AAPA to institute IPR is not judicially reviewable.

This Court’s *Qualcomm* decision does not require a contrary conclusion. There, this Court held that the Board misinterpreted § 311’s “prior art” language as including AAPA, 24 F.4th at 1369, whereas this appeal is “an ordinary dispute about the [Board’s] application” of that statutory requirement now properly interpreted, *Cuozzo*, 579 U.S. at 271-72; *see Appx31* (applying *Qualcomm*). Also, in *Qualcomm*, no party asserted unreviewability and this Court did not address that issue. *See Boeing N. Am., Inc. v. Roche*, 298 F.3d 1274, 1282 (Fed. Cir. 2002) (“[W]e are not bound by [a previous case] on [an issue] neither argued nor discussed in our opinion”). Moreover, § 314(d) is jurisdictional and thus not subject to forfeiture. *See Thryv*, 140 S. Ct. at 1372.

B. The Board Correctly Found The Petition Satisfies § 311(b) Because It Is Based On Prior Art, In View Of A Skilled Artisan’s Background Knowledge As Reflected In AAPA

Even if the Board’s § 311(b) determination is appealable, Shockwave’s challenge to the use of AAPA fails on the merits. The Board correctly found that AAPA was not “the basis” for CSI’s petition because it relied on numerous prior art references, so it met the threshold requirements under § 311(b). *Appx31* (quoting Updated AAPA Guidance (citing *Qualcomm*, 24 F.4th at 1377)). The petition presented—and the Board relied upon—a combination of patents and printed

publications and the background knowledge of a skilled artisan. In doing so, the petition and Board properly relied on AAPA as binding admissions by the patentee that can supply missing limitations. This Court has repeatedly held that this is an appropriate basis for invalidating claims in an IPR.

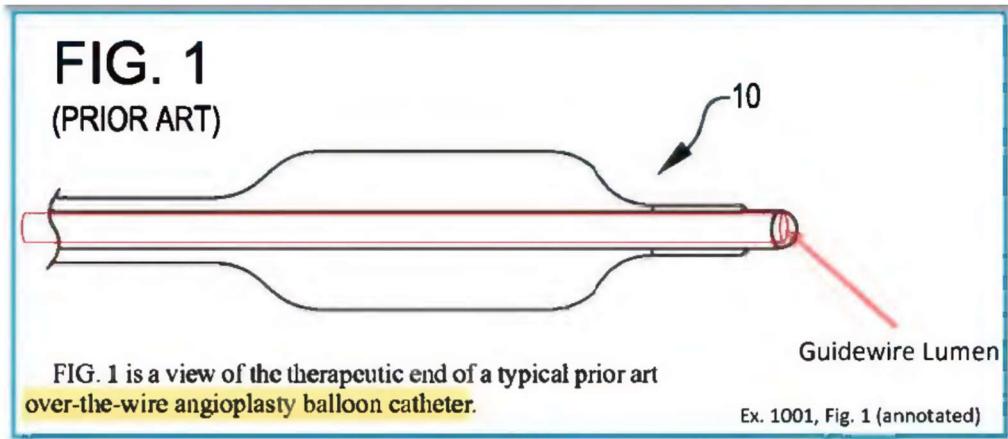
This Court addressed this issue in *Qualcomm*. There, this Court held that AAPA cannot itself be considered “prior art” that forms “the basis” for a petition under § 311(b). 24 F.4th at 1374. It is “impermissible for a petition to challenge a patent relying on solely AAPA without also relying on a prior art patent or printed publication.” *Id.* at 1377.¹ At the same time, this Court emphasized that the Board *can rely upon* AAPA as evidence of a skilled artisan’s knowledge and that the AAPA can supply missing limitations and motivation for obviousness. *Id.* at 1375-76. For good reason: AAPA is, by definition, an *admission by the patentee* about knowledge in the art, which this Court has long recognized is binding. *See Pharmastem*, 491 F.3d at 1362; *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1570 (Fed. Cir. 1998) (“A statement in a patent that something is in the prior art is binding on the applicant and patentee for determinations of anticipation and obviousness.”).

The Board correctly applied *Qualcomm* here. It recognized that a petition must be based on prior art references and that AAPA cannot be “the basis” under

¹ The PTO itself recognized as much in issuing its AAPA Guidance before *Qualcomm*. *See supra* at 13.

§ 311(b) but can “demonstrat[e] the background knowledge” of a skilled artisan. Appx31 (applying *Qualcomm*). The Board determined that the petition satisfies § 311(b) because each and every ground relies on “one or more of Levy, Mantell, Uchiyama, Willneff, Hayes, Duchamp, Naimark, and Beyar, all of which are prior art patents or printed publications.” Appx31 (citing Appx335-337); *see* Appx2-4. And the Board properly determined that the AAPA evidenced the background knowledge of a skilled artisan, demonstrating that angioplasty catheters with guidewire lumens were well known.

For example, the patent depicts (in Figure 1) and admits that a “typical” angioplasty catheter has a guidewire lumen (i.e., is “over-the-wire”)—and Shockwave itself depicted a guidewire lumen in that admitted prior art at the hearing:



Appx10495.

The Board properly relied on the patent’s admissions as evidence that the same arrangement would have been obvious. That was the same sort of reliance this

Court endorsed in *Qualcomm*. Indeed, it was especially appropriate here because the petition expressly defined “AAPA” as shorthand including not only the patent’s admissions but also knowledge of over-the-wire angioplasty balloon catheters found in “numerous” *other prior art references* like Healy and Hayes. Appx355 (“[F]or the sake of brevity, Petitioner refers to the typical prior art over-the-wire angioplasty balloon catheter described in the ’371 patent and as disclosed in Healy and Hayes herein as ‘AAPA.’”). Therefore, the Board’s reliance on the “AAPA” here is even more appropriate than relying on the applicant admissions in *Qualcomm*.

This Court’s decision in *Koninklijke* is also on point. There, this Court held that it was permissible for “general knowledge to supply a missing claim limitation in an inter partes review.” *Koninklijke*, 948 F.3d at 1337. So too here: CSI’s petition established that over-the-wire angioplasty catheters were well-known before the ’371 patent, and the Board properly relied on that evidence to conclude that the over-the-wire arrangement would have been obvious to a skilled artisan. Since “the inquiry into whether any ‘differences’ between the invention and the prior art would have rendered the invention obvious to a skilled artisan necessarily depends on such artisan’s knowledge,” that approach was proper. *See id.* (citation omitted).

Shockwave argues that the Board departed from the petition when it viewed the AAPA as evidence of background knowledge. Br. 22-25. But, as discussed, the petition used “AAPA” as shorthand for “the typical prior art over-the-wire

angioplasty balloon catheter”—which, in substance, plainly invokes background knowledge. Appx355. The Board applied that evidence in the same way: the AAPA described typical prior-art over-the-wire balloon catheters, rendering those aspects of the challenged claims obvious. The Board properly recognized that the petition invoked the AAPA for background knowledge even if the petition did not use that term *in haec verba*. *See, e.g., Sirona Dental Sys. GmbH v. Institut Straumann AG*, 892 F.3d 1349, 1356 (Fed. Cir. 2018).

Shockwave likens this case to this Court’s other holding in *Koninklijke*: that the Board was wrong to “institute[e] [IPR] based on a combination of prior art references not advanced in [CSI]’s petition.” Br. 24 (citing 948 F.3d at 1335). The situation here is different. In *Koninklijke*, the petition relied on a prior-art reference (Hua) solely as “‘evidence of the knowledge of a person [of] ordinary skill in the art,’” not as a reference in a ground. 948 F.3d at 1334 (alteration in original). The Board instituted IPR with the petition’s ground *and* a second ground that it described as a combination of another prior art reference with Hua. *Id.* at 1335. The Court held that the Board erred, explaining that “it is the petition, not the Board’s ‘discretion,’ that defines the metes and bounds of an [IPR]” and that the “Board does not ‘enjoy[] a license to depart from the petition and institute a *different* [IPR] of [its] own design.’” *Id.* at 1336 (citation omitted). In contrast, here, the Board

properly instituted the IPR on the same grounds the petition raised, not others. Appx2-4; *see Anacor Pharms., Inc. v. Iancu*, 889 F.3d 1372, 1380 (Fed. Cir. 2018).

At bottom, Shockwave's parsing of the differences in wording between the Board's decision and the petition elevates form over substance. The Board's decision properly considered the AAPA under *Qualcomm*.

C. The Board's Alternative Reliance On Healy and Hayes Independently Shows Guidewires Were Well-known

The Board further found that other prior art supplies the same information as the admissions in the patent. The Board found that the Healy and Hayes references, like the '371 patent, disclose typical over-the-wire balloon catheters. *See* Appx31-32. Substantial evidence supports that finding, and Shockwave does not dispute it. Accordingly, even without the AAPA, this other prior art confirms that over-the-wire catheters were "so well known" that they were obvious. Appx41. So even if the Board erred in relying on the in-patent admissions (and it did not), that would not change the outcome.

Shockwave argues that the petition did not invoke Healy and Hayes in sufficiently specific fashion. The Board rightly found otherwise: CSI relied on both Healy and Hayes in its petition specifically for their disclosure of "typical prior art over-the-wire angioplasty balloon catheter[s]." Appx355 ("Petitioner refers to the typical prior art over-the-wire angioplasty balloon catheter described in the '371 patent and *as disclosed in Healy and Hayes herein as 'AAPA.'*" (emphasis added)),

Appx336. As the Board observed, “the proposition for which [CSI] cited Healy and Hayes, the well-known configuration of an angioplasty catheter, was apparent on the face of Healy and Hayes.” Appx32. CSI also cited Healy and Hayes in its rehearing brief, pointing to specific passages that taught over-the-wire angioplasty balloon catheters. Appx1087-1108 at Appx1093-1094 (citing Appx3857-3859 (Healy Fig. 2, 1:50-60, 3:17-27, 3:37-38, 4:2-7); Appx1830 (Hayes Fig. 23), Appx1834-1835 (1:48-50, 3:56-58), Appx1839 (12:38-63), Appx1841 (15:25-26)). So Shockwave knew why CSI cited Healy and Hayes and what aspects were relevant—and had multiple opportunities to address them before the Board’s final decision.

Accordingly, Shockwave’s reliance on *Dell Inc. v. Acceleron, LLC*, 818 F.3d 1293, 1301 (Fed. Cir. 2016) (cited at Br. 27-28), is unavailing. In *Dell*, “the Board denied Acceleron its procedural rights by relying in its decision on a factual assertion introduced into the proceeding only at oral argument, after Acceleron could meaningfully respond.” *Id.* Not so here: CSI relied on Healy and Hayes from the start—it did not “introduc[e] new evidence on rehearing” (Br. 27)—and Shockwave had several opportunities to respond. The Board did not err in adopting CSI’s arguments. *See Corephotonics, Ltd. v. Apple Inc.*, 84 F.4th 990, 1010 (Fed. Cir. 2023); *Axonics, Inc. v. Medtronic, Inc.*, 75 F.4th 1374, 1383-84 (Fed. Cir. 2023); *Anacor*, 889 F.3d at 1380; *Amazon.com, Inc. v. ZitoVault, LLC*, 754 F. App’x 965, 972 (Fed. Cir. 2018).

Even if the Board erred in relying on Healy and Hayes (and it did not), it was harmless: the Board relied on them as *additional* evidence of the background knowledge of a POSA; the '371 patent discloses the same elements. Appx22-23, Appx31-32. With or without Healy and Hayes, the result is the same.

Under *Qualcomm*, the Board properly relied on the background knowledge of a skilled artisan, for whom over-the-wire catheters were undisputedly well-known, as reflected in the patent's admissions and in other prior art. Shockwave's arguments provide no basis to disturb the Board's decision.

II. THE BOARD CORRECTLY CONSTRUED “ANGIOPLASTY BALLOON”

The Board properly construed “angioplasty balloon” to mean “an inflatable sac that is configured to be inserted into a blood vessel for use in a medical procedure to widen narrowed or obstructed blood vessels.” Appx11-16. That construction is consistent with the claims, specification, and prosecution. The Board properly rejected Shockwave's unduly narrow interpretation, which required the angioplasty balloon to “displace[] the plaque *into the vessel wall*.” Appx11 (emphasis added). On appeal, Shockwave goes even further, importing a “high-pressure” requirement—which is likewise unsupported.

A. The Board Correctly Rejected Shockwave's Unsupported Requirement To Displace The Plaque "*Into The Vessel Walls*"

As the Board found, the claimed "angioplasty balloon" is inserted into a blood vessel and inflated "to widen narrowed or obstructed blood vessels"; it need not displace plaque "into the vessel wall" and is not otherwise limited to a particular type of balloon. Appx11-16. The Board's construction is correct under the intrinsic record, and the Board's fact-findings on the extrinsic record confirm it.

The plain claim language supports the Board's construction. Claim 1 recites, in relevant part:

an angioplasty balloon located near a distal end of the carrier with a distal end of the balloon being sealed to the carrier near the distal end of the carrier and with a proximal end of the balloon defining an annular channel arranged to receive a fluid therein that inflates the balloon

Appx200. The "angioplasty balloon" thus has certain features: it is located near the distal end of the carrier; its distal end is sealed to the carrier near the carrier's distal end; and its proximal end defines an annular channel arranged to receive a fluid that inflates the balloon. Appx200. But the claim does not require the balloon to displace plaque "into the vessel wall." Certain dependent claims add structural requirements, which underscores that claim 1 lacks those same requirements. *See* Appx200 (cls. 7-8) (stating balloon formed of "non-compliant" or "compliant" material); Appx11.

The specification likewise supports the Board's construction. Appx12. As the specification explains, in angioplasty procedures, the balloon is inflated to widen

narrowed or obstructed blood vessels. For example, the specification explains that, in angioplasty procedures, “a dilation catheter is used to cross a lesion in order to *dilate the lesion and restore normal blood flow in the artery.*” Appx198 (1:13-18) (emphasis added). The specification does not require displacing the plaque “into the vessel wall.” *See* Appx12. Indeed, the specification states that the balloon can be “expanded to fit snugly to the vessel wall … but *this is not a requirement.*” Appx200 (5:31-33) (emphasis added). As the balloon need not even “fit snugly” to the vessel wall, it follows that the balloon need not displace plaque *into* the wall.

In addition, the specification includes several examples that, consistent with the Board’s construction, describe or depict the balloon as inflatable to widen the blood vessel but say nothing about displacing plaque “*into* the vessel wall.” *See* Appx198 (1:40-45) (“The invention” includes a “dilating balloon” that is “arranged to receive a fluid therein that inflates the balloon”); Appx190-193 (Figs. 2, 4-9). For example, the specification explains that high-pressure shockwaves are used to “chip away the calcified lesion slowly and controllably expanding the opening in the vessel” (in Figure 11B) and the plaque is “pulverized by the shock waves” (in Figures 12 and 13). Appx200 (5:33-48). These shockwaves obviate the need to apply “excessive pressure by the balloon on the walls of the artery,” meaning the lesions are not being pressed much, if at all. Appx199 (4:36-41). As the lesion can be “chip[ped] away” or “pulveriz[ed],” it need not be displaced *into* the wall.

Moreover, in these examples, the plaque is *already in* the wall, so it makes little sense to require “displacing plaque ‘*into* the vessel wall’ from outside the wall.” Appx12 (emphasis added).

Two patents submitted during prosecution—“O’Boyle” and “O’Connor”—support the Board’s construction. Appx13-14; *see* Appx188 (citing O’Boyle and O’Connor). As the Board explained, those references refute Shockwave’s “*into* the wall” requirement. Both “merely describe compacting or pressing material ‘against’ rather than ‘*into*’ the wall of the vessel.” Appx13. O’Boyle states that, in prior art, “[b]alloon angioplasty require[d] the insertion into the blood vessel and through the stenosis of a deflated balloon, which [wa]s hydraulically inflated to stretch and compact the stenosis material against the wall of the artery.” Appx7640 (1:33-37). Similarly, O’Connor states that, in “a typical prior art balloon angioplasty arrangement,” the balloon when inflated “significantly opens the occluded part of the artery by pressing the thrombus against the internal wall of [the] artery.” Appx7652 (3:8-12); *see also* Appx7651 (1:14-18, 2:4-8) (noting that loose material could result from angioplasty).

Moreover, both references explain that their disclosed inventions operate by *removing* the build-up *using ultrasound*, not by crushing it against (let alone *into*) the wall. As O’Boyle emphasizes, “the inflation of the [angioplasty] balloon *does not* predominantly cause a *crushing* of the material of the stenosis *against the vessel*

wall.” Appx7641 (3:53-62) (emphasis added); *see also* Appx7634 (O’Boyle Abstract) (broken-up stenosis “is carried away by the blood flow” rather than “press[ed] … against the blood vessel wall”). O’Connor, meanwhile, explains that the balloon is inflated with low-pressure saline to contact the wall, then ultrasound creates “microfractures within the calcified plaque” to break it into “microparticulate matter.” Appx7652 (3:41-57). So both references confirm that an angioplasty balloon does not necessarily press plaque “*into* the vessel wall.” Appx13-14; *see Sequoia Tech., LLC v. Dell, Inc.*, 66 F.4th 1317, 1328 (Fed. Cir. 2023) (patentee’s citation of prior art during prosecution is relevant to construction).

The Board’s findings on the extrinsic evidence, although not necessary to the Board’s construction, further support it. Appx14-16. The dictionary definitions of “angioplasty” that Shockwave cited simply state, for example, that the balloon “compress[es]” or “push[es]” to “stretch the artery open.” *See* Appx5561-5562 at Appx5561 (WebMD); Appx5568-5571 at Appx5568 (MedlinePlus). As the Board found, these definitions “as a whole demonstrate that angioplasty refers more broadly to procedures that repair blood vessels and do not necessarily involve displacing material ‘*into* the vessel wall.’” Appx15; *see* Appx5561 (WebMD); Appx5563-5565 (Dictionary.com); Appx5568 (Medline Plus).

The Board also “heavily discount[ed]” and found not “credible” the testimony of Shockwave’s expert, Dr. Berger, who asserted that angioplasty requires

displacing plaque into the vessel wall and that “merely pressing plaque … against the vessel wall” is not enough. Appx15-16; *see* Appx14-15 (citing Appx7470-7472 (Berger ¶¶ 86-88); Appx4195-4196 (Berger Dep. 13:23-14:24)). The Board found his conclusion was unfounded because the evidence he relied on “establishes only that angioplasty involves the permanent deformation of a vessel”—it does not require displacement of the plaque into the wall. Appx15. The Board further found Dr. Berger’s testimony “irreconcilably inconsistent” with prior art that was before the Examiner during prosecution—O’Boyle and O’Connor—which, as discussed, “describe angioplasty as compacting material *against* the vessel wall.” Appx15. Substantial evidence backs the Board’s findings on the extrinsic evidence and further supports the Board’s construction. *See Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 322 (2015) (fact-findings underlying claim construction are reviewed with deference).

The Board’s construction was correct in view of the claim language, specification, prosecution, and extrinsic evidence.

B. Shockwave’s Arguments On Appeal Fail

On appeal, Shockwave argues that the Board’s construction is “too broad” and “lack[ing] … structure” (e.g., Br. 30, 9) but makes little effort to explain why Shockwave’s proposed “into the wall” construction was correct. Shockwave makes several arguments, each of which fails.

First, Shockwave reiterates its argument that an angioplasty balloon must press plaque into the vessel wall. Br. 28, 34-36. But, as discussed, that requirement is unsupported and the Board properly rejected it. Shockwave again relies on its expert testimony, *id.* at 28 (citing Appx7429-7430 (Berger Decl.)), which the Board “heavily discount[ed]” as conclusory. Appx15. The Board’s decision is correct and well-supported. *Supra* at 38-42.

Alternatively, Shockwave suggests that its construction does not mean the balloon must press the plaque “‘*into*’ the vessel wall” and that it is enough to merely press “‘*against*’ the vessel wall.” Br. 35 (emphasis added); *see id.* at 33. But Shockwave’s proposed construction plainly says “*into* the vessel wall,” and Shockwave’s own expert expressly opined that “against” and “*into*” are distinct concepts: “the device claimed by Shockwave *does not cover* balloons which merely press up *against* the vessel wall but do not force plaque *into* the vessel wall.” Appx7469 (Berger ¶ 83) (emphasis added); *see* Appx4195-4196 (Berger Dep. 13:7-14:10) (“Q. Does [the plaque] have to be pushed into the vessel wall from the lumen or can it just be crushed against the vessel wall? ... A. It has to be pushed into the vessel wall. ... [M]erely squishing the plaque is not enough”); Appx603 (POR) (citing Appx7469 (Berger ¶ 83)); Appx15-16. And Shockwave points to no evidence that a skilled artisan would understand “*into*” and “*against*” to mean the

same thing in this context. The Board properly rejected Shockwave’s overly narrow “into the wall” proposal. *Supra* at 38-42.

Second, Shockwave asserts that angioplasty requires inflating balloons to “high pressures of 10-30 atmospheres.” Br. 4; *see id.* at 29, 33, 34, 36, 37 (arguing balloon must be inflated to “high pressure” to break up plaque). But Shockwave did not make that argument in its POR (thus not preserving it) and, instead, apparently *disavowed* any specific “pressure” requirement. *See Appx609 (POR)* (“Patent Owner acknowledges that angioplasty balloons can use mechanisms *other than pressure* to treat plaque, so long as the end result is for the angioplasty balloon to displace plaque into the vessel wall.” (emphasis added)).²

In any event, Shockwave’s new construction fails on the merits because the claims and specification nowhere recite a “high pressure” requirement (let alone “high pressures of 10-30 atmospheres”). To the contrary, requiring the balloon to exert “high pressures” undermines the stated purpose of the invention. The patent

² Moreover, Shockwave did not apply this new “high pressure” construction to its own device in its secondary-considerations arguments. Nor could it, as Shockwave’s balloon is “inflated at a pressure of 4 [atmospheres]” to deliver energy impulses, *Appx8054* (emphasis added)—which is well below the “10-30 atmospheres” Shockwave insists its claims require, Br. 4; *see also Appx1052* (Shockwave’s counsel: “[I]t’s the ability of the shockwaves to do great work without damaging healthy tissue, and because those shockwaves can impact the calcium, *we need less pressure for the angioplasty balloon.*” (emphasis added)). This Court should decline Shockwave’s invitation to read claim 1 one way for the obviousness analysis and another, conflicting way for secondary considerations.

explains that, in prior art, the use of high pressures in angioplasty was a *problem* that the patent purported to recognize and solve. Appx198 (1:31-36) (“As the pressure builds a tremendous amount of energy is stored in the balloon until the calcified lesion breaks or cracks. That energy is then released and results in the rapid expansion of the balloon to its maximum dimension and may stress and injure the vessel walls.”). The purported invention works *without* requiring the balloon itself to create high pressures: shockwaves travel through the fluid in the balloon “to the calcified lesion where energy will break the hardened plaque *without the application of excessive pressure by the balloon* on the walls of the artery.” Appx199 (4:36-41) (emphasis added).

The prior art confirms that Shockwave’s “high pressures” argument is unfounded. O’Boyle describes an angioplasty balloon that is inflated to less than *four* atmospheres and explains that “high inflation pressures” are not required. Appx7642 (5:15-22), Appx7643 (7:41-45), Appx7644 (10:47-51, 59-64). O’Connor’s balloon is similarly only inflated “to a *moderate* pressure (1 to 3 atmospheres).” Appx7652 (3:38-39) (emphasis added); *see also* Appx1834 (Hayes 1:27-29) (“[a] typical medical balloon will burst at approximately 7-20 atmospheres”). Therefore, a skilled artisan would have understood that angioplasty balloons are not necessarily inflated to the high pressures (10-30 atmospheres) that Shockwave urges.

Third, Shockwave contends that, during prosecution, the applicant disclaimed claim scope when it added “angioplasty” to overcome a rejection over Mantell. Br. 32. This argument fails. Such a disclaimer must be clear and unmistakable. *Thorner v. Sony Comput. Ent. Am. LLC*, 669 F.3d 1362, 1367 (Fed. Cir. 2012).

There is no clear and unmistakable disclaimer requiring an “angioplasty balloon” to displace plaque “into the vessel wall.” Indeed, the prosecution passage that Shockwave cites *never mentions* those (or equivalent) words. See Appx601-602 (POR) (citing Appx2242-2249 at Appx2247 (remarks on amendment)). At most, the applicant stated that Mantell was not “configured for vessel dilation.” Appx2247. But that prosecution passage says nothing about displacing anything “into the vessel walls” and is consistent with the Board’s construction, which provides that the angioplasty balloon “widen[s] … blood vessels.” Appx16. In that passage, the applicant further noted that other types of balloons—“e.g., Swan-Ganz catheter balloons, embolectomy catheter balloons, wedge pressure balloons, occlusive balloons, etc.”—are “functionally and structurally distinct from an angioplasty balloon.” Appx2247. But, there again, the passage never suggests that the reason those types of balloons are “distinct” is because they do not displace plaque into the vessel wall. See Appx2247. Nor did the Examiner do so in later allowing the claims. Appx1962-1967. The prosecution history, therefore, offers no

support (clear and unmistakable or otherwise) to import an “into the wall” requirement, or any other, into the claims.

Shockwave further contends the Board erred in failing to consider the prosecution. Br. 31-33. That argument is unavailing. The Board considered and rejected Shockwave’s prosecution history arguments in its institution decision, observing that “[e]ven if the amendment of claim 1 were to exclude Mantell’s balloon, ... Petitioner relies upon Levy and AAPA, not Mantell, as describing the claimed balloon.” Appx545. So it was unnecessary “to resolve the specific extent of potential disclaimer of scope associated with ‘angioplasty balloon’ through the amendment of claim 1 allegedly to distinguish Mantell.” Appx545. There was no reason for the Board to revisit the prosecution-history statements in its final decision because Shockwave did not argue the Board was wrong in concluding that the supposed disclaimer did not implicate Levy. *See* Appx601-604 (POR). Moreover, as discussed, the prosecution history does not support Shockwave’s limiting “into the wall” construction.

Fourth, Shockwave’s remaining arguments fare no better. Shockwave argues the Board’s construction was “extremely broad” and failed to “require the structure of an ‘angioplasty balloon.’” Br. 28-29, 34. But Shockwave does not explain what that means or how those arguments support its proposed construction. If Shockwave is arguing that the claims require “into the wall” or “high pressure” requirements,

those fail for the reasons discussed. *Supra* at 38-47. If Shockwave implies some other requirement, it did not raise it before and does not explain it now.

The Board correctly construed “angioplasty balloon.”

C. The Board Found The Claims Obvious Under Either Construction

There is no dispute that, under the Board’s construction, Levy discloses an “angioplasty balloon.” *See* Br. 36-37; Appx28. But the Board found the claims obvious under either construction because the AAPA undisputedly discloses an angioplasty balloon, even as construed by Shockwave. *See* Appx28-29 (“Second, Patent Owner’s argument fails to address Petitioner’s showing that the AAPA describes an angioplasty balloon.” (citing Appx356 (Pet.))). The Board further found there was motivation to add the AAPA’s angioplasty balloon to Levy if Levy did not already include one. Appx38-41.

Shockwave suggests that CSI did not argue—and the Board did not find—that a skilled artisan would have added the AAPA’s angioplasty balloon to Levy. Br. 37-38. However, CSI argued that a skilled artisan, “looking to adapt Levy’s catheter and/or balloon design to increase the types of treatments Levy could perform, would have been motivated to look to other catheters and balloons ..., including the AAPA—i.e., the ‘most common angioplasty catheter and balloon design.’” Appx40 (quoting Appx754); *see* Appx754 (citing Appx1644-1645 (¶ 115), Appx1664-1665 (¶ 157)). The Board agreed. Appx41. In addition, the Board’s “motive to

incorporate a[n] AAPA Guidewire and Sealing Arrangement into Levy” necessarily entails a motivation to add the angioplasty balloon: that configuration was so well known that “no dispute exist[ed] that … angioplasty balloon catheters having a guidewire extending through a carrier to which *the angioplasty balloon* is sealed near its distal end were well known.” Appx38 (emphasis added).

In other words, the Board’s finding on incorporating the prior art’s guidewire into Levy necessarily included incorporating the angioplasty balloon: the two were inextricably intertwined. Indeed, Shockwave did not separately contend—in its Preliminary Patent Owner’s Response or its POR—that there was no motivation to combine the AAPA’s angioplasty balloon with Levy. *See Appx442; Appx652-657.* Shockwave cannot now fault the Board for not saying more. *See Paice LLC v. Ford Motor Co.*, 881 F.3d 894, 905 (Fed. Cir. 2018) (“[T]he Board’s analysis is commensurate with [those] arguments.”).

* * * * *

The Board correctly construed “angioplasty balloon” and rejected Shockwave’s unsupported limiting construction. In addition, the Board properly found the limitation obvious under either construction.

III. SUBSTANTIAL EVIDENCE SUPPORTS THE BOARD'S OTHER OBVIOUSNESS FACT FINDINGS

Shockwave next challenges three Board fact findings, but substantial evidence supports each: (1) a skilled artisan would have been motivated to incorporate a guidewire lumen into Levy's catheter design; (2) Levy and other prior art disclose shockwaves; and (3) Shockwave's secondary considerations evidence was, separately and collectively, "largely weak" and did not outweigh CSI's obviousness showing. For each, Shockwave urges the Court to reweigh the evidence, discard credibility determinations, and make new fact findings. The Court should not do so.

A. Substantial Evidence Supports the Board's Conclusion that a POSA Would Have Been Motivated to Incorporate a "Guide Wire Lumen" Into Levy

The Board found that "an ordinarily skilled artisan would have had motive to combine teachings of Levy with the background knowledge reflected in the AAPA to arrive at the claimed configuration of the balloon sealed near the distal end of a carrier through which a guidewire extends." Appx41. That finding is well supported.

First, there was "no dispute" that "angioplasty balloon catheters having a guidewire extending through a carrier to which the angioplasty balloon is sealed near its distal end were well known." Appx38. The '371 patent admitted that this configuration was "prior art." Appx38-39 (citing Appx199 (3:66-67, 4:31-33)). Other prior art of record confirmed it was ubiquitous. Appx1843-1851 at Appx1844

(Duchamp Application Figs 1-3), Appx1848 (¶ 21) (“guidewire 33 suitable for advancement through a patient’s coronary arteries”); Appx3855 (Healy Abstract), Appx3857 (Fig. 2), Appx3859 (3:17-27) (“Guidewire lumen 28 can slidingly accept a guidewire 72.”); Appx4689-4690 (Lennox Figs. 1, 3), Appx4695-4696 (4:63-5:8) (“Lumen 12 extends from the proximal end of catheter shaft 10 to the distal end, and provides a conduit for guidewire 46.”); Appx7649 (O’Connor Figs. 2, 3), Appx7652 (3:26-51) (“Catheter 20 will typically” have a “lumen[] ... to slide over a guidewire”). In addition, during prosecution of the ’371 patent, the Examiner similarly concluded that the arrangement was well-known—and the applicant did not dispute it. Appx2242-2249, Appx2256. The Board identified and relied on all of this evidence—and Shockwave again did not dispute it. *See* Appx39, Appx41. The Board’s finding is not conclusory (*cf.* Br. 39-40); it is well supported.

Second, substantial evidence supports the Board’s finding that there was a motivation to incorporate the ubiquitous guidewire lumen into Levy’s device. Shockwave contends the Board did not properly identify such a motivation. Not so.

The Board found there were at least two reasons to incorporate a guidewire lumen into Levy: (1) “to assist a physician to navigate the catheter to reach the area for treatment,” Appx39, and (2) ““to increase the types of treatments Levy could perform,”” Appx40 (quoting Appx754). The Board cited Dr. Jensen’s testimony to support each. Appx39-40 (citing Appx1643 (Jensen ¶ 112), Appx1644-1645

(¶ 115)); *see Appx1643* (¶ 112) (“The use of a guidewire to assist the physician to navigate the angioplasty catheter through tortuous passages to reach the area for treatment is well known to the skilled artisan.”), *Appx1645* (¶ 115) (“It would have been obvious for the person of ordinary skill in the art to have implemented and utilize the most common angioplasty catheter and balloon design, with predictable and expected results.”). Dr. Jensen would know the purpose of a guidewire lumen in a balloon catheter: he was present during, and actively participated in, numerous cardiology procedures and experiments. *Appx1608* (¶ 12).

In addition, a guidewire lumen’s purpose of assisting a physician to navigate the catheter through the body was well-established in prior art. *See, e.g., Appx1848* (Duchamp ¶ 21) (guidewire allows “advancement through a patient’s coronary arteries”). So the Board’s finding is again supported, not conclusory (*cf. Br. 40*). *See Vanderlande Indus. Nederland BV v. ITC*, 366 F.3d 1311, 1321 (Fed. Cir. 2004) (crediting expert testimony based on personal experience); *Snyder v. Sec’y of Health & Hum. Servs.*, 553 F. App’x 994, 1000 (Fed. Cir. 2014).

Shockwave further asserts that “the existing structure of Levy” is “utterly incompatible with a guidewire lumen.” Br. 41. That is incorrect. Levy itself recognizes that it is not limited to the specific balloon structure that Shockwave focuses on; rather, Levy’s balloon “may have the shape of a balloon of the kind that is used with catheters used to perform treatments in Blood vessels” and need only

have “a high degree of flexibility.” Appx1737. The specific structure Shockwave points to is a dependent claim, showing that Levy’s independent claim is not so limited. *See* Appx1741 (cl. 3). In other words, Levy contemplates different balloon structures, including for angioplasty balloon catheters, which were well known by Levy’s May 1992 filing date, as discussed. *Supra* at 4. In addition, “[t]he test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference.” *Allied Erecting & Dismantling Co. v. Genesis Attachments, LLC*, 825 F.3d 1373, 1381 (Fed. Cir. 2016) (citation omitted). The question is whether “a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention.” *Id.* (citation omitted). The Board properly found such motivation here.

Because substantial evidence supports the Board’s conclusion that a skilled artisan would have been motivated to incorporate a well-known guidewire lumen into Levy, the Court should affirm the Board’s determination.

B. Substantial Evidence Supports The Board’s Conclusion that Levy Discloses Shockwaves

The Board also properly found that Levy discloses shockwaves.

Levy incorporates by reference Levy ’227 and describes its “pulsed laser radiation” that “causes a cavitation of vapor within the liquid, which results in the implosion of gas bubbles, this implosion causing erosion of the deposit exposed to the cavitation phenomenon.” Appx1735. Levy goes on to explain the necessity for

cooling the liquid in that type of system and describes an invention aimed at “remov[ing] deposits formed on the walls of a passage, using the energy provided by the pulses of a laser beam, with increased security.” Appx1735-1736. So the Board was correct to conclude that Levy incorporated Levy ’227’s laser beam pulses. *See Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000) (documents incorporated by reference are “effectively part of the” document).

Shockwave does not dispute that Levy incorporates Levy ’227 by reference or that Levy ’227 discloses shockwaves. Br. 45. Instead, Shockwave contends that Levy ’227 does not disclose using shockwaves *in blood vessels*. *Id.* at 45-46. That is incorrect. Levy ’227 first teaches that “[c]leaning of [tooth or radical] canal 1 is achieved by shock waves resulting from the laser radiation pulses, producing vapor implosions which detach debris or tissue from the wall of canal 1.” Appx3657 (3:39-42); *see also* Appx3657 (3:46-61) (“each radiation pulse” produces “[a] shock wave”). It then explains that this shockwave technique “can also be employed in the medical field for cleaning vessels, *such as blood vessels*.” Appx3657 (4:64-66) (emphasis added); *see also* Appx3656 (2:31-34) (“The mechanism described above may also advantageously be used for disintegrating plaque or atheromas *in blood vessels* or similar deposits in other body passages, such as urinary canals.”) (emphasis added)). Levy ’227 notes that “the parameters of the radiation pulses are selected

on the basis of the nature of the vessel and its diameter.” Appx3657-3658 (4:67-5:2). When the device is introduced into the vessel, the tube’s interior is filled with a physiologic solution to create pressure, which “creates a favorable environment for the cavitation action,” Appx3658 (5:13-17)—the same cavitation that results in shockwaves. *See* Appx3657 (3:31-45).

According to Shockwave, the language indicating that radiation-pulse parameters are adjustable shows that Levy ’227’s blood-vessel embodiment uses different pulses that do not create shockwaves. Br. 46-47. But Shockwave identifies no evidence showing that, when discussing cleaning blood vessels, Levy ’227—which explicitly discloses using shockwaves in every other context—somehow intended to communicate that lower-energy pulses resulting in non-shockwave cavitation were necessary. That is inconsistent with Levy ’227’s explicit language, which describes the use of higher-energy pulses in blood vessels (5-200mJ, Appx3658 (5:20-23)) than in tooth canals (0.5-5mJ, Appx3657 (3:54-57)) and states that shockwaves result from “*each* radiation pulse” and that “[t]he [same] technique can ... be employed in the medical field for cleaning ... blood vessels.” Appx3657 (3:58-61, 4:64-66) (emphasis added). The Board’s findings on Levy ’227 were reasonable and thus supported by substantial evidence. *See Teva Pharms*, 8 F.4th at 1359.

Unable to point to anything in Levy '227 that limits the cavitation action to sub-shockwave levels, Shockwave invokes extrinsic evidence that supposedly teaches away from using shockwaves in blood vessels. *See Br.* 48. But Shockwave made the same argument to the Board to suggest that EHL probes were considered too dangerous to use in blood vessels, and the Board rejected it. *See Appx32-35.* That finding, which Shockwave does not challenge on appeal, applies with equal force to Levy '227's teachings and precludes Shockwave's argument here. *Cf. Provisur Techs., Inc. v. Weber, Inc.*, 50 F.4th 117, 125-26 (Fed. Cir. 2022) (applying Board fact findings consistently across different claims).

Lastly, Shockwave suggests that the Board erred in failing to identify a motivation to combine Levy '227's dental treatment with Levy's angioplasty device. *Br.* 47. That assumes that the two are different embodiments in separate references, and they are not: Levy incorporates Levy '227's radiation pulses for use in blood vessels, which Levy '227 itself explained was an option. *Supra* at 9, 53-55. By definition, incorporating Levy '227 by reference means that it is treated as if set forth fully within Levy. *See Advanced Display*, 212 F.3d at 1282. Because of that incorporation-by-reference, the Board did not need to identify a motivation to combine Levy '227 with Levy. *See Callaway Gold Co. v. Acushnet Co.*, 576 F.3d 1331, 1346 (Fed. Cir. 2009) (concluding that prior-art patent incorporating another by reference anticipated asserted claims); *Vicor Corp. v. SynQor, Inc.*, 603 F. App'x

969, 975-76 (Fed. Cir. 2015) (reversing Board decision of no motivation to combine because one reference incorporated the relevant teachings of the other).

Whether Levy '227 discloses shockwaves is, ultimately, an academic question: the Board also found that a skilled artisan would have been motivated to incorporate the arc generators in any of Mantell, Uchiyama, and Willneff into Levy to arrive at the claimed shockwave generator. *See Appx30-31.* Each is sufficient to affirm the Board because each discloses generating shockwaves between electrodes positioned within a balloon. *See Appx30* (citing Appx1759-1760 (Mantell Figs. 1, 2), Appx1763-1764 (Figs. 5-7), Appx1776-1777 (¶¶ 21, 24, 29); Appx1784-1786 (Uchiyama Figs. 1-7); Appx1799, Appx1804-1805 (Willneff); Appx1646-1648 (Jensen ¶¶ 117-19)). Importantly, Shockwave never argued otherwise to the Board, nor does it now argue that the Board was incorrect on that point. *See Appx30* (“Patent Owner does not respond to Petitioner’s showing that each of these three references describes using arcs between electrodes within a balloon to generate shockwaves.”). The Court should, therefore, affirm the Board’s determination that the claimed shockwaves were obvious.

C. Substantial Evidence Supports The Board’s Findings Evaluating Shockwave’s Evidence Of Secondary Considerations

Shockwave next challenges the Board’s conclusions on Shockwave’s evidence of purported secondary considerations of non-obviousness, arguing that the Board “disregard[ed]” that evidence. Br. 53. Not so. Over 18 pages of analysis, the

Board carefully considered each piece of evidence Shockwave identified and made factual findings on the weight it assigned to it. *See Appx47-65.* As substantial evidence supports each finding, the Court should affirm the Board’s conclusion that secondary considerations do not make the challenged claims patentable.

1. The Board Properly Found No Presumption Of Nexus

As an initial matter, the Board found that Shockwave was not entitled to a presumption of nexus. Appx47-49. Substantial evidence supports that finding.

To establish a presumption of nexus, a patentee must show “that the asserted evidence is tied to a specific product and that the product ‘*is* the invention disclosed and claimed.’” *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019) (citation omitted). Before the Board, Shockwave sought a presumption of nexus based on a single paragraph (¶ 201) of Dr. Berger’s testimony. Appx661-662 (POR) (citing Appx7541-7543 (Berger ¶ 201)); *see Br. 53-55* (relying exclusively on Dr. Berger). The Board, however, recognized that this testimony “does not link the claims to the structure of [Shockwave’s] commercial device,” and Shockwave apparently intended to cite the chart in the prior paragraph (Appx7539-7541 (Berger ¶ 200)). Appx47. But the Board also found that chart insufficient because it does not explain the actual claim language and “fails to address expressly whether the Shockwave IVL device” includes several limitations. Appx49. The Board, therefore, found that Shockwave “simply fails to carry its burden of persuasion that

the claims cover its product, much less that the two are sufficiently coextensive to be entitled to a presumption of nexus.” Appx49.

That was a reasonable conclusion, especially as Dr. Berger never saw Shockwave’s device except in pictures and could not say who prepared the claim charts he cited. Appx4247 (Berger Dep. 219:15-220:13) (“Q. Did you create those? A. I didn’t create the charts. … Q. Do you know who did? A. No.”); Appx4198 (23:7-24:2), Appx4252 (240:7-16); Appx48. Without Dr. Berger’s testimony, Shockwave had no support for its presumption-of-nexus arguments. *See* Br. 53-55. Shockwave faults the Board for not considering Exhibit 2196 (Appx8926-8931). Br. 54. But Shockwave itself did not rely on that exhibit for a presumption of nexus, *see* Appx661-662 (POR) (citing only Berger ¶ 201); Appx842 (Sur-reply), instead citing it only in discussing commercial success, Appx678 (citing Ex. 2196); Appx7556 (Berger ¶ 224) (same). Shockwave, therefore, cannot fault the Board on that front. *See Paice*, 881 F.3d at 905; *cf.* Br. 54-55. The Board properly found Shockwave failed to show a presumption of nexus.

Moreover, Shockwave is not entitled to the presumption as a matter of law. Shockwave admits that its IVL device is not coextensive with claim 1 of the ’371 patent and that other patents cover it: its counsel conceded at the hearing that “there are some unclaimed features from the other two [IPR] proceedings that are included in the device.” Appx1073. Where, as here “[a] patent claim is not coextensive with

a product that includes a ‘critical’ unclaimed feature that is claimed by a different patent and that materially impacts the product’s functionality,” it is not entitled to a presumption of nexus. *Fox Factory*, 944 F.3d at 1375. Therefore, Shockwave did not show that its supposed “evidence of secondary considerations is the ‘direct result of the unique characteristics of the claimed invention.’” *Id.* at 1373-74 (citation omitted).³ Shockwave’s secondary considerations arguments fail at the threshold.

2. The Board Properly Weighed Shockwave’s Evidence And Found It Insufficient To Save The Claims

Even though Shockwave failed to justify a presumption of nexus, the Board analyzed Shockwave’s purported objective indicia anyway. Appx49. Those findings are correct and amply supported by substantial evidence. In its detailed 15-page analysis, the Board examined each piece of evidence Shockwave identified (as to purported long felt need, failure of others, skepticism, industry praise, and commercial success), making findings on the weights assigned to each and to the relevant factor generally. Appx50-65; *see supra* at 18-19. The Board then explained that, cumulatively, Shockwave’s evidence was “largely weak for all the reasons that [the Board] express[ed].” Appx65. The Board found that “excitement about the *potential* efficacy of the Shockwave IVL or its *potential* commercial success” was

³ Indeed, Shockwave relied on the same purported success of its IVL products to try to save its patents in the other two IPRs and made no attempt to apportion the purported success to each patent; the Board (like here) rejected Shockwave’s arguments, and this Court affirmed. *See supra* at x; Appx1004 (29:24-26).

not sufficient to overcome the Board’s other findings of obviousness. Appx65. Those fact-findings are sound and should not be disturbed.

On appeal, Shockwave principally argues that this Court’s decision in *Volvo Penta of the Americas, LLC v. Brunswick Corp.*, 81 F.4th 1202, 1215 (Fed. Cir. 2023), “is exactly on point.” Br. 57; *see id.* at 55-59. It is not. In that case, this Court found that the Board’s decision lacked substantial evidence for several reasons. In particular, although the Board itself found that there was copying, industry praise, and commercial success, it nonetheless afforded these factors only “some weight,” without explaining why. *Volvo*, 81 F.4th at 1213-14. The Board also “failed to properly evaluate long-felt but unresolved need” because it ignored, without explanation, portions of an article that “indisputably identifie[d] a long-felt need.” *Id.* at 1214. Moreover, “[t]he Board d[id] not discuss the summation of the factors at all other than to say, without, explanation, that they collectively ‘weigh[] somewhat in favor of nonobviousness.’” *Id.* at 1215 (citation omitted).

The Board made none of those mistakes here. The Board properly discussed each factor, explained its reasoning, and addressed in detail the evidence Shockwave presented. The Board found no long-felt need—or failure of others—because, although “IVL is a promising treatment,” there remain other “viable treatment options that may have advantages in certain circumstances.” Appx59; *see* Appx50-60. The Board rejected Shockwave’s skepticism argument because “an ordinarily

skilled artisan would have had a reasonable expectation of successfully making a working device” as claimed. Appx60. The Board afforded Shockwave’s purported industry praise “some, but not great, weight” because the “genuine excitement” ultimately rested on “unsubstantiated speculation about better efficacy” and “often forward-looking statements from financial analysts or hopeful statements.” Appx61. The Board also found that Shockwave’s commercial success evidence was “weak” because, *inter alia*, it “wholly fails to establish the amount of market share attained by [Shockwave’s] devices” and relies on uncertain revenue projections. Appx63-64. Moreover, unlike in *Volvo*, the Board here explained its summation: it found Shockwave’s secondary considerations evidence showed “excitement about the *potential* efficacy of the Shockwave IVL or its *potential* commercial success”—and thus was “largely weak.” Therefore, the Board’s decision here suffers none—let alone all—of the flaws this Court identified in *Volvo*.

The rest of Shockwave’s sundry arguments merely seek to revisit the Board’s fact-findings and should be rejected. *See Inwood Laboratories, Inc. v. Ives Laboratories, Inc.*, 456 U.S. 844, 856 (1982) (“Determining the weight and credibility of the evidence is the special province of the trier of fact.”).

First, on commercial success, Shockwave argues that the Board only considered its revenue *projections*. Br. 56. But the Board considered Shockwave’s evidence of revenue increases and noted that Shockwave’s “increased spending on

sales and marketing at least partially explains the increase in its revenues.” Appx62. Shockwave also incorrectly suggests that the Board erred in requiring Shockwave to show market share. Appx62. The Board properly explained that evidence of commercial success without market-share data is less probative, and it concluded that Shockwave’s evidence was “weak,” showing that, consistent with this Court’s precedent, it afforded the evidence at least some weight. *See* Appx63-64; *see also In re Huang*, 100 F.3d 135, 140 (Fed. Cir. 1996) (“This court has noted in the past that evidence related solely to the number of units sold provides a very weak showing of commercial success, if any.”). Shockwave further suggests that the Board ignored that Shockwave’s IVL device “created a new market.” Br. 56. But Shockwave did not make that argument in its POR or present any such evidence to the Board—it only made that assertion in its Preliminary Patent Owner’s Response, Appx402, and did not further pursue it or support it with evidence.

Second, on long-felt need and industry praise, Shockwave argues the Board dismissed one article’s laudatory statements as “prospective” (Br. 58), but does not dispute the factual accuracy of that finding, nor could it. As the Board found (Appx58-59), that article is overtly prospective. *See* Appx8067 (Ex. 2131) (“We believe that IVL balloon *is going to* transform the market, as it is easy to use, with predictable results and in most centers *it will* replace cutting and scoring balloons for the treatment of calcific disease. The advent of the IVL balloon *may*

revolutionize this indication but cost-effectiveness of these advanced technologies will need to be considered.” (emphasis added)). Shockwave also argues the Board ignored Exhibit 2130. Br. 58. But that article was likewise non-committal: it observed that “lithoplasty balloon *seems to be* a transformational technology” but “confirmatory data are still required.” Appx8054 (emphasis added). That article, therefore, supports the Board’s findings that the secondary-considerations evidence focused more on the invention’s “*potential*” not its *actual* success, and thus did not confer patentability. Appx65.

Shockwave also challenges the Board’s reliance on the “Dill” paper. Br. 58. The Board found that Dill showed there were other available treatments for calcified lesions (e.g., “rotational atherectomy,” which was “more effective than traditional angioplasty balloons”—and thus undermined Shockwave’s “contention that Shockwave IVL was the only treatment available for such lesions.” Appx53 (citing Appx8022). Shockwave does not contest that conclusion but contends Dill is irrelevant (as Dill “does not address IVL at all”) and “the Board nowhere explained why it relied on” Dill. Br. 58. That argument is misplaced because Dill was *Shockwave’s own evidence* (Appx7535-7536 (Berger ¶ 194 (citing Dill)) and the Board explained that it relied on it as showing that other *non-IVL* treatments were available. Substantial evidence supports the Board’s finding.

The Board’s findings on secondary considerations are sound and supported by substantial evidence. *See Elbit*, 881 F.3d at 1358.

IV. THE BOARD DID NOT ABUSE ITS DISCRETION IN DENYING SHOCKWAVE’S REQUEST TO REOPEN DISCOVERY

Shockwave next contends that the Board abused its discretion in refusing to reopen discovery in light of CSI’s 2022 press release. Br. 60-63. But such case management functions fall within the Board’s discretion. *See Quake*, 928 F.3d at 1379-81 (“Board was within its discretion to not reopen the record”). Under Board rules, Shockwave needed to show that its requested additional discovery was in “the interests of justice.” 37 C.F.R. § 42.51(b)(2)(i). The Board determined that Shockwave did not meet that high bar, and that was not an abuse of discretion.

Shockwave argues on appeal, as it did before the Board, that CSI’s 2022 press release (regarding CSI’s new proprietary IVL system) somehow contradicted CSI’s arguments on secondary considerations (regarding prior IVL and predecessor systems). Br. 60-62. According to Shockwave, the Board “did not even consider CSI’s striking change in position.” Br. 16. But the Board *did* consider Shockwave’s argument and properly found there was *no* inconsistency. Appx89-91.

In its secondary-considerations arguments, CSI explained to the Board that IVL was not the *only* treatment that met the standard of care for treating heavy calcification extending into the medial layer and that existing IVL systems—including Shockwave’s system—faced challenges in terms of efficacy and safety.

Appx757-759 (Reply). That is consistent with CSI's 2022 press release, which is a forward-looking statement about CSI's new proprietary IVL balloon catheter system and how it may improve upon the limitations of existing technology. Appx10649-10650. The press release did not suggest that other treatments are ineffective or less effective than IVL at treating heavily calcified lesions, nor did it discuss the safety of Shockwave's IVL device or of IVL generally. Appx10649-10650. The press release simply announced the uncontroversial fact that CSI was expanding its medical toolkit. Appx10649-10650. Thus, as the Board found, "the Press Release contains nothing that materially conflicts with the existing record." Appx91.

In addition, the Press Release explicitly acknowledged that its statements necessarily "involve risks and uncertainties that could cause results to differ materially from those projected," including as to "the development of the new IVL systems" and potential "expansion of market opportunities." Appx10650. The Board found that "the 'risks and uncertainties' in the Press Release statements about [CSI]'s potential market expansion drastically diminish the probative value of those statements in determining how to weigh objective evidence of nonobviousness." Appx91. Shockwave does not address that additional finding, which alone supports the decision.

Instead, Shockwave misconstrues the press release to find inconsistency. Shockwave repeatedly asserts that CSI said that *Shockwave's IVL device* "has been

used successfully for many years.” *See, e.g.*, Br. 61 (quoting Appx10649). But, in fact, the press release stated that “[l]ithotripsy has been used successfully for many years *in the treatment of kidney and gall stones*, and more recently has *found application* in treatment of calcified coronary and peripheral arteries.” Appx10649 (emphasis added). That is consistent with CSI’s explanation that other treatment options for calcified lesions were available before the ’371 patent. The Board’s finding that the press release did not warrant reopening the record was well-supported, not an abuse of discretion.

In sum, the Board’s obviousness determination on claims 1-4 and 6-17 of the ’371 patent is correct, supported by substantial evidence, and should be affirmed.

V. THE COURT SHOULD REVERSE THE BOARD’S DETERMINATION UPHOLDING CLAIM 5

The Board should have held claim 5 obvious as well. Claim 5 recites that “the pair of electrodes is disposed adjacent to and outside of the guide wire lumen.” Appx200. That location for the electrodes is a simple design choice, as reflected in Uchiyama (Appx1784-1786) combined with the other prior art references. *See* Appx363; *see also* Appx1653 (Jensen ¶¶ 132-33); Appx4071-4072 (Jensen Supp. ¶ 144); Appx7358-7359 (Jensen drawings); Appx755 (Reply).

The Board, however, upheld claim 5 because purportedly “Uchiyama fails to describe” this limitation. Appx68. That was legal error for two reasons: the Board (1) incorrectly considered Uchiyama in isolation (rather than in the prior art

combination as a whole) and (2) failed to recognize that claim 5’s limitations were, at most, a mere design choice. Each independently warrants reversal on claim 5. But before turning to the merits, CSI addresses Shockwave’s standing argument.

A. CSI Has Standing To Cross-Appeal On Claim 5

Shockwave argues the Court should dismiss the cross-appeal for lack of standing. Br. 1. The Court should reject that argument.

To appeal a Board decision, a party “must meet ‘the irreducible constitutional minimum of standing,’” including by showing, as relevant here, an injury in fact. *Amerigen Pharms., Ltd. v. UCB Pharma GmBH*, 913 F.3d 1076, 1082 (Fed. Cir. 2019) (citation omitted). An injury in fact must be “concrete and particularized,” “not conjectural or hypothetical.” *Spokeo, Inc. v. Robins*, 578 U.S. 330, 339 (2016).

Where, as here, a party challenging an IPR decision “relies on potential infringement liability as a basis for injury in fact, but is not currently engaging in infringing activity, it must establish that it has concrete plans for future activity that creates a substantial risk of future infringement or would likely cause the patentee to assert a claim of infringement.”” *Gen. Elec. Co. v. Raytheon Techs. Corp.*, 983 F.3d 1334, 1341 (Fed. Cir. 2020) (“*General Electric II*”) (quoting *JTEKT Corp. v. GKN Auto. Ltd.*, 898 F.3d 1217, 1221 (Fed. Cir. 2018)). Thus, a party need not have a “product on the market at the present time” and “need not face ‘a specific threat of

infringement litigation by the patentee”” to have Article III standing. *Id.* at 1341-42 (citation omitted).

CSI has standing to bring its cross-appeal for two independent reasons: (1) “it has concrete plans for future activity that creates a substantial risk of future infringement,” and (2) its activity is “likely [to] cause the patentee to assert a claim of infringement.” *Id.* at 1341 (citation omitted).

First, CSI has made substantial progress developing in IVL device that will compete with Shockwave’s. The design is in its final stages, and clinical trials will begin in the near future, as CSI’s Vice President of Research and Development explained. ECF No. 21-2 (“Cambronne Decl.”) ¶¶ 4-7, 11; *see* ECF No. 21 at 4-6, 8 (Opp. Mot. Dismiss). That progress, on its own, represents “activity that creates a substantial risk of future infringement.” *General Electric II*, 983 F.3d at 1341 (citation omitted).

Second, Shockwave publicly vowed to accuse CSI’s product of infringement as soon as it launches. By way of background, on December 7, 2018, CSI sought IPR of three Shockwave patents covering IVL systems: the ’371 patent at issue here and two others. The Board instituted trial on all three. During the IPRs, CSI made efforts to resolve all current and future patent disputes, including the IPRs, but Shockwave refused to engage. *See* Cambronne Decl. ¶ 16. The Board ultimately

issued Final Written Decisions in July 2020, invalidating every challenged claim in all three patents except for claim 5 of the '371 patent.

Immediately thereafter, on July 8, 2020, Shockwave's President/CEO, Doug Godshall, publicly asserted that "any viable, much less commercially viable, IVL device must contain" the elements of claim 5. ECF No. 20-2 at CSIAppl1 (emphasis added). Shockwave then appealed the decisions invalidating the other two patents, and this Court summarily affirmed both on January 18, 2022. *See supra* at x. By then, CSI had publicly disclosed that it was developing an IVL system and intended to compete in the IVL market. Ex. 2, CSIAppl3-4. By January 13, 2022, "[f]easibility testing of a proprietary console and associated IVL balloon catheters [was] complete," and CSI "plan[ned] to begin first in-human experience for the peripheral IVL system in calendar 2023." CSIAppl3.

Then, with rehearing on the '371 patent ongoing, Shockwave reiterated its intent to sue CSI for infringement. On February 17, 2022, Mr. Godshall publicly stated that Shockwave will "certainly" assert its patent against anyone who "tries to copy" Shockwave's IVL approach. Ex. 3, CSIAppl23. In the IPR itself, in urging the Board to reopen discovery into CSI's in-development IVL device, Shockwave repeatedly asserted that CSI's product embodied the claims of the '371 patent. *See, e.g.*, Appx10585 (Feb. 22, 2022 Hrg. Tr.) ("[I]t's certainly reasonable to infer their product will be covered"); Appx1243 (Mot. for Additional Discovery) ("[T]he

fact that CSI uses the same term ‘IVL’ to describe its new product is (at a minimum) highly suggestive that CSI’s IVL device includes this key claimed feature.”).

Therefore, Shockwave’s public statements—including its unambiguous assertion that it will assert claim 5 of the ’371 patent against “*any* viable … IVL device” (ECF No. 20-2 at CSIAppx1, CSIAppx23)—show that CSI’s IVL product development is “likely [to] cause the patentee to assert a claim of infringement.” *General Electric II*, 983 F.3d at 1341. Accordingly, CSI has established standing to appeal the Board’s decision with respect to claim 5.

B. The Board Erred In Upholding Claim 5

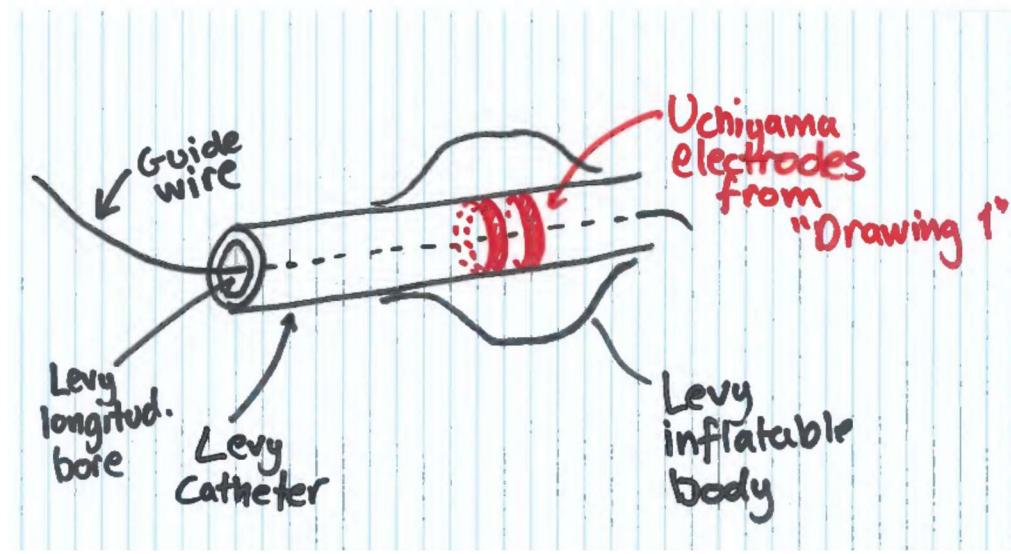
The Board made two errors in upholding claim 5. Reversal is warranted.

1. The Board Erred in Considering Uchiyama In Isolation Rather Than In The Prior-Art Combination As A Whole

A proper obviousness analysis requires the Board to consider the prior art’s combined teachings. *See In re Mouttet*, 686 F.3d 1322, 1333 (Fed. Cir. 2012). The Board did not do so for claim 5. *See* Appx67-70. Rather, the Board found that Uchiyama alone did not disclose “a pair of electrodes that are both ‘adjacent to and outside of the guidewire lumen’ as required in claim 5.” Appx70.

That was error because CSI’s petition relied on Uchiyama in combination with other prior art as teaching claim 5’s limitation. In particular, CSI’s petition relied on “Levy as Modified by AAPA In Combination With Mantell or Uchiyama or Willneff.” Appx363. The petition explained that a skilled artisan would find it

obvious—“a routine design choice”—to locate a pair of electrodes (as depicted in Uchiyama) adjacent to and outside (i.e., “radially spaced away from”) the guidewire lumen. Appx363-364 (Pet.); *see also* Appx755 (Reply) (“A POSITA thus would have understood from Uchiyama that the electrodes could be displaced radially away from the lumen tube to, for example, permit the shockwaves to obtain greater lateral (i.e., side-ways) coverage”); Appx69 (Uchiyama Drawing 1). Petitioner’s expert, Dr. Jensen, explained and depicted how this would look in combination with Levy and the AAPA, as shown below.



Appx7359; *see also* Appx7358.

The Board did not address this combination. Instead, the Board determined that Uchiyama *alone* does not show that the electrodes are disposed outside of the lumen tube and, based solely on that finding, held that CSI failed to show claim 5 is obvious. *See* Appx69-70. Even assuming that is correct, the Board erred in failing

to consider the asserted combination as a whole. *See Mouttet*, 686 F.3d at 1333; *Provisur*, 50 F.4th at 125 (“Because the Board never directly or implicitly addressed the arguments that Weber had set forth in its petition, it erred.”). For that reason alone, the Board’s holding on claim 5 should not stand.

2. Placing The Electrodes Outside The Guidewire Lumen Was A Routine Design Choice

The Board further erred in upholding claim 5 because the claimed electrode placement was, at most, a routine design choice that would have been obvious to try.

In *KSR*, the Supreme Court “set forth an expansive and flexible approach” to “the question of obviousness,” especially as to “design choices and predictable variations.” *Uber*, 957 F.3d at 1338 (quoting *KSR Int’l v. Teleflex Inc.*, 550 U.S. 398, 415 (2007)). “When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp.” *KSR*, 550 U.S. at 421.

Here, as CSI argued in its petition, it would have been a “routine design choice” to place the electrodes outside the lumen. Appx364; *see* Appx1653 (Jensen ¶ 133). Logically, there were “a finite number” of possible locations for the electrodes—either inside or outside the lumen. But Uchiyama teaches that the electrodes must be within the fluid in the balloon in order to transmit the charge to the lesion. *See* Appx1785 (“electric discharge sparks are generated inside of the

balloon[7] by the pair of the electrodes[3]” and “the impact ... is transmitted to the calculus S via the fluid inside of the balloon[7]”). So, in the Levy combination, that means the pair of electrodes must be outside the lumen, as Dr. Jensen depicted, because that is where the balloon and fluid are located. *See supra* at 4-5, 9-11, 71-73. The Board therefore erred in not finding that claim 5’s limitation was an obvious routine design choice that a POSA could have implemented with a reasonable expectation of success.

KSR and *Uber* are instructive. In *KSR*, the Court held that it would have been obvious to use a fixed pivot point pedal to permit mounting a position sensor to achieve an adjustable electronic pedal because that was one of “a finite number of identified, predictable solutions” known to a POSA. 550 U.S. at 421. Similarly, in *Uber*, this Court held that, contrary to the Board’s decision, it would have been obvious as a matter of law to use “server-side plotting” (as claimed) because it was one of only two possible locations, the alternative being “terminal-side plotting.” 957 F.3d at 1338-39. Similarly, here, there are two options for the electrodes: inside the guidewire lumen or outside of it, and only the latter makes sense in the asserted combination. Claim 5 is, therefore, obvious and the Board erred and lacked substantial evidence in holding otherwise.

3. Reversal Is Warranted On Claim 5

The Court should reverse rather than vacate the Board's decision on claim 5 because, once the prior art combination is considered as a whole and a skilled artisan's design choices are taken into account, the record allows only one reasonable conclusion: claim 5 is obvious. *See supra* at 71-74; *Uber*, 957 F.3d at 1341-42 (reversing, not vacating). In its Patent Owner's Response, Shockwave's only argument against CSI's proposed placement of the electrodes in the Levy combination was that they would have been too close to the tissue, causing damage. Appx658. But the Board rejected that same argument in making its other obviousness findings. *See* Appx32-35 (explaining why Shockwave's evidence did not support its assertion that a skilled artisan would have considered EHL probes too dangerous to use in blood vessels).

Therefore, under the proper legal analysis, the only plausible conclusion is that placing the electrodes outside the guidewire lumen, as recited in claim 5, is just as obvious as the other claim limitations. Accordingly, this Court should reverse that determination. At minimum, the Court should vacate and remand on that issue.

CONCLUSION

The Court should affirm the Board's determination that claims 1-4 and 6-17 of the '371 patent are unpatentable and reverse the Board's determination upholding claim 5.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(g)(1), I hereby certify that the foregoing opposition complies with the type-volume limitations in Federal Rule of Appellate Procedure 27(d)(2)(A). According to the word count feature of Microsoft Word, the opposition contains 16,481 words, excluding the exempted parts under Federal Rule of Appellate Procedure 32(f). The opposition has been prepared in a proportionally spaced typeface using Times New Roman in 14 point size.

Date: December 14, 2023

Respectfully submitted,

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